Minutes from the April 23, 2015

CDC Advisory Committee to the Director

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Advisory Committee to the Director: Record of the April 23, 2015 Meeting
The Centers for Disease Control and Prevention (CDC) convened a meeting of its Advisory Committee to the Director (ACD) on April 23, 2015 at the Tom Harkin Global Communications Center in Atlanta, Georgia. The agenda included updates and discussion regarding global health security (GHS); CDC's response to the Ebola outbreak in West Africa; recent domestic viral outbreaks of Middle East Respiratory Syndrome (MERS), Enterovirus D68 (EVD68), and Measles; antibiotic resistance (AR) initiatives; CDC laboratory safety improvements; and ethical considerations of CDC's public/private partnerships. The agenda also included updates from the ACD Health Disparities Subcommittee (HDS); State, Tribal, Local and Territorial (STLT) Subcommittee; Global Work Group (GWG); External Laboratory Safety Workgroup (ELSW); and Public Health - Health Care Collaboration (PHHCC) Workgroup.

Welcome and Introductions
Dr. Alan Greenberg (ACD Chair) called the meeting of the Advisory Committee to the Director, Centers for Disease Control and Prevention at 8:42 a.m. EDT. Those present and on the telephone introduced themselves. An attendance roster is appended to this document as Attachment #1. A quorum of ACD members was present, and quorum was maintained throughout the duration of the meeting. Senior CDC staff members attending the meeting introduced themselves. The following ACD members disclosed conflicts of interest:

- Dr. Georges Benjamin said that the American Public Health Association (APHA) has a cooperative agreement with CDC as well as a series of small grants.
- Dr. Nisha Botchwey is a recipient of the Partnerships to Improve Community Health (PICH) grant.
- Dr. David Fleming works for PATH, which receives some grants from CDC, none of which are directly to him.
- Dr. Lynn Goldman is Dean of the Milken Institute School of Public Health at George Washington University, which receives cooperative agreement funding from CDC. None of the agreements involves her directly.
- Dr. Jewel Mullen is the Connecticut Public Health Commissioner. They are CDC grantees. She is also the president of the Association of State and Territorial Health Officials (ASTHO), a recipient of CDC funding. She is on the board of the Public Health Accreditation Board (PHAB).
- Ms. Sara Rosenbaum said that the Department of Health Policy and Management at George Washington University occasionally works with CDC on policy projects.
- Dr. Alan Greenberg's department at George Washington University indirectly receives funding from CDC through the DC Department of Health.

Director's Update
Dr. Thomas R. Frieden (Director, CDC) presented ACD with an overview of CDC activities and invited input regarding making the agency more effective as it pursues its goal to optimize health. CDC's strategic directions are to improve health security domestically and internationally and to prevent the leading causes of illness, injury, disability, and death. CDC approaches this work by strengthening the connection between public health and healthcare.

CDC's fiscal year (FY) 2015 budget level is approximately $6.9 billion. This budget level was an increase of approximately $39 million compared to the prior year. It also established a Working Capital Fund. CDC received approximately $1.8 billion in emergency funding in response to Ebola and to improve global health security (GHS). CDC's budget also incorporates the Prevention and Public Health Fund (PPHF), which is part of the Patient Protection and Affordable Care Act (ACA). CDC works to ensure that the PPHF supports initiatives with broad

bipartisan support, such as immunization, cancer, and birth defects. For the first time last year, Congress opted to allocate the PPHF.

The proposed CDC budget for FY 2016 includes two large initiatives to address antimicrobial resistance (AMR) and prescription drug overdose (PDO). Other important increases in the proposed budget include:

- Doubling the viral hepatitis program
- Expanding the National Healthcare Safety Network (NHSN)
- Conducting more youth and evaluation work in human immunodeficiency virus (HIV)
- Adding more preparedness materials through the Strategic National Stockpile (SNS)
- Strengthening global health capacity, which is critically important given efforts to end Ebola
- Continuing progress in eradicating polio
- Expanding the select agent program and its investigations
- Focusing on climate change
- Building on the PDO Prevention Program
- Addressing laboratory safety

The request to increase CDC's budget is relatively modest, and it is counterbalanced by decreases in certain areas. Some decreases may remain in the final budget, and some may be reinstated by Congress. The block grants and some National Institute for Occupational Safety and Health (NIOSH) programs are proposed for elimination every year and are restored every year.

The West Africa Ebola outbreak of 2014 was worse than all other Ebola outbreaks combined. CDC's response to the outbreak was the agency's largest mobilization in its history. At the peak of the outbreak, the situation was horrific. The healthcare system essentially shut down, and it is likely that there will be more deaths from non-Ebola causes, such as malaria and tuberculosis (TB), caused by the Ebola problem rather than by Ebola itself. Treating routine infections and pneumonia is also challenging.

The World Health Organization (WHO) reported the first cases of Ebola on March 23, 2014. CDC had a team in the field within a week of the report. In April and May 2014, it appeared that the outbreak was controlled. Additionally, the CDC teams where not particularly welcomed by the WHO offices in that part of the world. The CDC teams left Africa, which was a mistake in retrospect. New cases in the capital of Guinea and the first cases in Sierra Leone were reported. In June 2014, cases resurged throughout Guinea and new cases were identified in Liberia and Monrovia. On June 23, 2014, Médecins Sans Frontières/Doctors Without Borders (MSF) reported that the outbreak was out of control, with almost 500 cases and 300 deaths.

On July 9, 2014, CDC activated the Emergency Operations Center (EOC) and instituted new waves of deployments to the region. By the end of July 2014, 100 staff members were deployed. Nigeria reported its first cases on July 25, 2014 and 40 Nigerian physicians trained in polio work were deployed to work in that EOC, which was run by a manager experienced in polio. On August 1, 2014 CDC released a series of guidances on screening and infection control. WHO declared a public health emergency of international concern on August 8, 2014. By that time, there were 1800 Ebola cases and 1000 deaths. CDC laboratories in West Africa began field testing in August. In September 2014, Monrovia experienced explosive spread of Ebola, and it was clear that the epidemic was out of control.

Dr. Frieden visited the region at the end of August 2014. CDC did everything within its power to fight the epidemic, working closely with other US government entities including the US Department of Defense (DoD). CDC provided infection control training and published its modeling on September 26, 2014. The modeling exercise showed the possibility of a substantial number of cases, with exponential growth. It also showed that each month of delay in response would triple the number of cases, and that the penalties for delay would be extraordinary. Further, the modeling projected a "tipping point" at which reaching 70% safe burial and 70% safe care of cases would lead to exponential decreases in cases. This finding drove the strategy of rapidly deploying burial teams and working toward safe care, whether in a formal Ebola Treatment Unit (ETU) or a community setting. The model was accurate in the shape of the epidemic curve. The actual case rate was one tenth of the worst-case scenario case rate. Under-reporting of cases was approximately 2.5 fold, so there were likely between 20,000 to 23,000 cases. It is important to emphasize that the modeling showed what would happen if nothing was done. The predictions galvanized action by illustrating the potentially horrific outcome of inaction.

The first US case of Ebola was identified on September 30, 2014. By then, there were 6500 cases and 3000 deaths in West Africa. A "funneling strategy" was instituted in October 2014, in which all returning travelers to the US from affected countries were screened at five airports and then tracked by local health departments. The Rapid Isolation and Treatment of Ebola (RITE) strategy in Liberia was implemented. If response teams could arrive in an area within a few days to a week, transmission could be stopped within a couple of generations. Rather than having a few hundred or a few thousand Ebola cases, this strategy could keep the case count down to a few dozen. The sooner teams arrived in affected areas, the sooner the outbreak could be ablated. Duration was cut in half when RITE was implemented, and survival rates doubled. There was progress in controlling Ebola in January 2015, but there was increased spread in Guinea in February 2015 in urban areas. The Sierra Leone Trial to Introduce a Vaccine Against Ebola (STRIVE) study was initiated in March 2015. Liberia has not had a new case in 60 days.

The global toll of Ebola is more than 25,000 cases and more than 10,000 deaths. There have been over 2000 deployments, with 924 staff deployed to West Africa and more than 3000 staff working in the EOC. Every Epidemic Intelligence Service (EIS) officer has worked on Ebola. More than 12,000 laboratory tests have been conducted at CDC laboratories in West Africa; 25,000 health workers have been trained; 150,000 travelers have been screened for Ebola; and 13,000 travelers have been tracked in the US, with over 200,000 individual contacts. The 25 travelers who have had symptoms either had malaria, influenza, or an unknown diagnosis. None had Ebola. Eleven patients were treated for Ebola in the US, and 55 hospitals in the US have been approved to treat Ebola patients. Since the outbreak, 56 laboratories have been approved for Ebola testing. CDC has issued more than 150 technical guidance documents. CDC has one of the most visited websites in the federal government and among all health sites, and the number of unique visitors increased to 35 million in October 2014.

It is important to get ahead of the curve now, as July and August are the peak of the rainy season, and mobility is a significant challenge. Ebola has been cleared from many parts of the region, but challenges remain in parts of Sierra Leone and Guinea. CDC and its partners have been working on innovations to address Ebola, including rapid diagnostics. A private company created an integrated polymerase chain reaction (PCR) machine which can generate results in 90 minutes. Another important innovation is a lateral flow assay that can yield a result from blood or saliva in 20 to 30 minutes. It will enter field trials soon to determine its sensitivity and specificity, and it will be helpful to generate preliminary results in areas that do not have

electricity. ZMapp is the most promising Ebola medicine. Its trial is progressing. The National Institutes of Health (NIH) has completed Phase II testing in Liberia. In Guinea, WHO and the European Union (EU) are conducting a cluster trial. CDC is working on a healthcare worker vaccination trial in Sierra Leone. The US has worked with 44 countries to sign a signal agreement to implement key policies of the Global Health Security Agenda (GHSA). CDC is working with DoD to implement pilot projects in many countries. There are many crosswalks between GHS and Ebola. GHS policies will make the world safer from Ebola.

GHS is not just focused on preparing for adverse health events. It also focuses on building capacity that allows for health progress. Efforts in Haiti are similar to efforts in West Africa. After Haiti's earthquake and cholera epidemic, CDC began a series of programs to eliminate lymphatic filariasis, improve vaccine coverage, introduce new vaccines, and double the number of people receiving antiretroviral therapy (ART). The benefits of GHS extend to protecting the poorest countries, and the poorest populations within those countries. There are health and economic benefits associated with strengthening countries' capacity to implement any health program they choose to implement and with building sustainable systems for vaccines or for addressing AMR. GHS utilizes a "health in all policies" approach to involve other sectors such as education and security.

AMR is a major budget initiative for CDC in FY 2015. In 2013, CDC issued a report that focused on drug resistance as a phenomenon, estimating that at least 2 million infections and at least 23,000 deaths annually in the US are due to AMR. This issue is an economic threat and a threat to modern medicine. Routine medical treatment relies on the ability to cure infections, especially for persons receiving chemotherapy or whose immune systems are suppressed due to other health concerns. CDC's budget includes $246 million to slow the development of AMR and reverse resistance where possible to prevent its spread. Other efforts regarding AMR include strengthening surveillance systems, advancing rapid diagnostics, and supporting research and partnerships for prevention. The plans include establishing a detection network of seven regional laboratories and centers of excellence to characterize emerging resistance and to rapidly identify and respond to outbreaks. The number of emerging infection sites will be doubled to 20. Protection programs will be established in all 50 states and in large cities to include antibiotic prescribing and to track how resistance circulates within the community. Other work will focus on understanding the microbiome and how it relates to AMR. Enhancing international collaboration and scaling up of rapid detection are also important initiatives.

The two deadliest threats are carbapenem-resistant *Enterobacteriaceae* (CRE) and *Clostridium difficile* (*C. diff*). CRE is in every state, and it must be stopped before it leaves the hospital. CRE rates can be driven down by 60% in five years, and *C. diff* can be driven down by 50% in five years. With appropriate resources devoted to the problem, it is possible to prevent more than 600,000 multidrug-resistant (MDR) infections and 37,000 deaths and to save nearly $8 billion in medical costs.

CDC's second major initiative for the coming year is prescription drug abuse which, like AMR, is related to overuse of medications which have large, recognized risks and fewer benefits for some patients than previously recognized. The US is in the midst of a horrific epidemic of prescription opioid overdose and, more recently, of heroin overdose. Rates of opioid prescription are very high. Up to one-third of women of childbearing age on Medicaid are prescribed opioids. It may be tempting to assume that the increases in heroin overdose and death are due to the crackdowns on prescription opioids. This relationship may exist in some individual cases, but overall, the heroin phenomenon is independent of the prescription drug problem. Heroin is become cheaper and more plentiful. The largest increases in heroin deaths

are occurring in areas where increases continue in PDO deaths. One set of people are dependent or addicted and need services. Another set of people are at risk for addiction and dependence.

The success of motor vehicle safety offers some important lessons learned. These efforts represented partnerships between communities, public health, and law enforcement. Deaths due to motor vehicle crashes have been cut in half. This work included interesting interplay between social norms and legal measures. As drunk driving became less socially acceptable, laws to punish drunk driving became more feasible to pass. At the same time, the laws made drunk driving less socially acceptable. The same kind of interplay is needed for addiction.

A possible technical package for prescription opioid misuse, overdose, and abuse prevention could include:

- ❑ Improving prescribing
- ❑ Improving treatment, including access, quality, and accountability, for both addiction and overdose
- ❑ Reducing the availability of illicit drugs
- ❑ Promoting social awareness and economic development to reduce initiation and continuation of drug use
- ❑ Rigorous and real-time monitoring, evaluation, and optimization of appropriate action

Laboratories are critical to CDC's mission and for GHS. The next budget requests $20 million to maintain and strengthen laboratories while allowing for more training, more information technology (IT) work, and the implementation of the recommendations of the External Laboratory Safety Workgroup (ELSW). CDC has established a new Laboratory Leadership Service (LLS) program. This two-year, post-doctoral fellowship is patterned after the EIS program. It will focus not only on the science of safety, but also on the need for leadership and management. Seven fellows are participating this year, and the program will continue to grow.

Discussion Points

Dr. Farley asked which approaches were most important to the control of Ebola. There was a sense that the ETUs required a great deal of effort and were too little, too late. He also asked about the relative importance of home treatment and isolation and burial teams versus center-based treatment in stopping spread of the virus.

Dr. Frieden replied that those questions were considered in detail in Liberia over a 12-week period. There are some urban myths regarding burial. Safe burial is critically important, and it is possible to experience an explosive spread of Ebola from just one unsafe burial. During the 12-week period in Liberia, approximately 1100 deceased individuals were picked up by burial teams. At the same time, approximately 2000 individuals were admitted to ETUs, of whom approximately 60% died. Those deaths received safe burials and had received safe care for some portion of their illness. Safe care and safe burials are both important initiatives, but the safe burials had a larger impact. When he visited the area in August 2014 and reviewed the modeling with political leaders and the incident manager, it was clear that no international response would be fast enough to stem the spread. Community isolation was important and was somewhat familiar in Africa because of smallpox treatment approaches. Efforts to isolate people in homes were failures, as there was no way to care for them safely. Efforts to provide safe places for people to receive care were successful, and were initiated by communities throughout Liberia. Leaders from every district in Liberia were convened in groups to engage in microplanning exercises. As the Ebola numbers decreased, the response transitioned from a

"bury and build" phase to a "track and trace" phase. CDC staff were pivotal for both phases, as they provided guidance for specifications for the burial teams and established strategies. The DoD presence was critical as they provided equipment and supplies, trained thousands of healthcare workers, built ETUs, and provided laboratory support. Perhaps most importantly, the DoD presence brought hope to countries that feared that the world would abandon them. Support from other governments and non-governmental organizations (NGOs) has also been critical, particularly in Guinea, which has a large population and large area, but a smaller CDC staff. On the whole, the response is an example of effective public health action, which includes community engagement.

Ms. Rosenbaum asked for details regarding the statistics of women of childbearing age on Medicaid who are prescribed opioids.

Dr. Frieden answered that CDC published a recent *Morbidity and Mortality Weekly Report* (*MMWR*) with data from a number of sources indicating that opioid prescription rates among women of childbearing age are 20% to 25% in the non-Medicaid population, and 25% to 30% in the Medicaid population. These medications are highly addictive and highly lethal if an individual takes even a little bit too much. The risk/benefit ratio of these drugs is wrong. He recalled that he heard one lecture on pain in medical school, in which the professor stated that opioids are not addictive. That is not true. It is not easy to change the culture, however, and that challenge is similar for antibiotic overuse.

Ms. Rosenbaum asked about the kinds of conditions for which the opioids are prescribed and whether the overuse epidemic might be related to types of employment.

Dr. Frieden said that CDC has considered that question and concluded that the problem relates more to prescribing practices and social norms than to employment sectors. There is an outbreak of HIV in Scott County in Southern Indiana. The town of Austin's population is 4300, and as many as one in six adults uses intravenous (IV) drugs. There are already 130 diagnosed HIV cases in the county, nearly all of which also have hepatitis C. Over 100 contacts remain to be assessed, and those positive cases will lead to additional contacts. The number of people infected with HIV through IV drug use in Austin is greater than the number of people infected with HIV through IV drug use in all of New York City in 2014.

Dr. Jonathan Mermin said that 35 states in the US have experienced increases of over 75% in hepatitis C acute cases in the past few years, but there has not been an increase in HIV among drug users. One of the greatest successes in HIV in the last 20 years has been an over 80% reduction in the active number of diagnoses of HIV among drug injectors. The increases in use of prescription opioids and the increasing heroin epidemic portend the potential for increases in hepatitis C and HIV outbreaks. In 2014, a nurse in Scott County, Indiana noticed an increase of approximately 11 HIV cases, and now there are over 100 cases. The Indiana Health Department led an outbreak control program. The response has three levels: make diagnoses, find and diagnose their contacts, and control the current epidemic. Another level of work includes determining whether similar outbreaks are occurring elsewhere in the US using available surveillance related to HIV and hepatitis C as well as related to overdose deaths and substance use treatment. Another approach includes expanding on programs that will prevent similar outbreaks in the future. The situation in Indiana is unprecedented, and responding effectively is critical on all levels.

Dr. Mullen thanked CDC for the support it provides to state and local health officials regarding Ebola. This support came in addition to the 24/7 support that CDC already provides. She noted

that many people may not understand the success associated with all of CDC's hard work and wondered how to tell the story and help people understand that the work continues even as they have had some success.

Dr. Frieden invited input from the ACD on those points. CDC is focused on getting Ebola cases to zero in West Africa and on achieving clear, quick successes regarding GHS. There is better understanding of the importance of health among global leaders now than ever before. Resources should be devoted well and quickly to show success stories. This work is not easy, and many countries do not have well-developed health or governmental infrastructures. Domestically, there can be better understanding regarding the importance of improving infection control and outbreak detection and response in hospital systems. Because trends are not tracked well and whole genome sequencing is not utilized, many outbreaks related to AMR are not detected. He expressed his hope for better understanding of the importance of state health departments in AMR-related interventions so that all areas of healthcare in communities are connected.

Regarding Ebola, Dr. Greenberg noted that the enormous response to an epidemic that defies words required a tremendous amount of resources. He wondered what has been lost as manpower and funding have been devoted to Ebola. Documenting and responding to these questions will be important.

Dr. Frieden answered that it is hard to describe the effect of the Ebola response on CDC. At one time, over 800 people, nearly 10% of the agency's professional staff, were working on Ebola, where typically that number is closer to 20. Some other functions happened more slowly, and priorities had to be set. The entire agency helped as Ebola was the top priority.

Dr. Beth Bell said that the National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) has seven divisions. In the fall of 2014, five of the seven division directors were deployed, and the others were working nearly full-time on Ebola from Atlanta. There was a freezing of many important initiatives, and personnel prioritized the day-to-day activities that had to occur. The AMR initiative crosses the agency, but its leadership resides in NCEZID in the same division that is responsible for infection control, which worked on Ebola infection control domestically and in affected countries in West Africa.

Ms. Carmen Villar added that while initiatives were delayed, the agency is finding balance and catching up now. All of the EIS officers have worked on Ebola, and many of them have indicated their appreciation for being involved.

Dr. Anne Schuchat said that two of the four division directors in the National Center for Immunization and Respiratory Diseases (NCIRD) are still deployed. Because of the ongoing response, her center has experienced delays in immunization recommendations even as urgent work continued.

Dr. Frieden acknowledged that while the agency is catching up now, it has been a year like no other for CDC personnel. While the work has been a privilege, it has also been exhausting.

Dr. Rima Khabbaz added that staff have been stretched, but they have not documented exact effects.

Dr. Goldman appreciated the overview of CDC's future directions. She acknowledged that while CDC necessarily put some things on hold, state and local health agencies also experienced

heavy demands. In general, public health is good at responding to crisis situations, but there are impacts. She said that the relationship between CDC and state and local health agencies was clear during the Ebola response. Those relationships are also important in environmental health. She asked about nurturing those relationships and capacity further, noting that global climate change is one of CDC's "asks." The health impacts of climate change are emerging as priority issues among deans of public health schools.

Dr. Frieden said that CDC is part of a federalist system and therefore supports state and local health departments. During an emergency, central command and control is important; however, health and public health are domains not specifically assigned to the federal government, and therefore they are the domains of the states. State and local entities will always be the most aware of their own constraints, opportunities, and strengths. At the same time, the system is as weak as its weakest links. Dallas and New York City, where the two domestic Ebola cases were located, have very strong health departments. If that were not the case, the situation would have been much more difficult. Additionally, policy issues such as how to address returning travelers, vary by states. Support to state, tribal, local, and territorial health departments is a significant priority for CDC, and that support has included increased funding, additional imbedded staff members, and additional training opportunities.

Dr. Bal said that state and local health officials do what needs to be done. CDC has historically served as the think tank for the content of public health activities through the infectious disease era, the chronic disease era, and now the environmental era, providing the scientific basis for state and local action. Many state and local health departments are floundering regarding where public health interacts with the new, evolving healthcare sector. Most hospitals in the US were in violation of the Community Health Needs Assessment (CHNA) provision of the ACA in 2013. In 2016, many of them will still be in violation. CDC has the intellectual capital to address these situations and to provide guidance.

Dr. Frieden agreed that the most challenging issue for public health in the US in the next decade will be its intersection with healthcare. The issue touches virtually every aspect of CDC. The agency models a close relationship with the Centers for Medicare and Medicaid Services (CMS), including extensive interaction, project management, and technical input. CDC is identifying a core set of issues that can help CMS help their providers to do better (e.g., blood pressure control, tobacco use cessation, unintended pregnancy prevention, infection prevention, asthma control, and diabetes prevention and control). These six areas represent a "sweet spot" with sufficient interest in their likelihood of cost savings on the part of the healthcare systems, and with sufficient importance within public health and the likelihood of making a difference. CDC is establishing clear packages in these areas. The healthcare world is extremely complex, but there are examples, such as immunization, of successful public health initiatives and guidance. He hoped that state health departments and Medicaid programs will work more closely as CDC and CMS are working more closely.

Dr. Bal emphasized that CDC has special technical prowess and is unique among federal agencies in its relationship with state and local health departments. CDC's role as the "mother ship" for public health makes it crucial that CDC interface with the Internal Revenue Service (IRS) regarding the CHNA requirements and other aspects of the ACA.

Dr. Frieden said that CMS is the lead agency for the ACA, and CMS has been very open to working closely with CDC. An example of this work is the State Innovation Models (SIM) Initiative.

Dr. Fleming recalled times in which the public health system has not acted in unison and has been internally dysfunctional. The Ebola outbreak turned a corner and saw the system come together and make rapid decisions. These achievements are a testament to CDC's leadership and engagement with state and local entities. Ebola took a toll on the public health system at the state and local levels as well as at the CDC level. The public seemed to expect state and local systems to be able instantly to put systems into place. Engaging in this work resulted in time lost at the state and local levels, and other issues had to be de-prioritized.

Ebola Response Update
Dr. Daniel Jernigan (Ebola Response Incident Commander) addressed ACD regarding the Ebola outbreak in West Africa, which is the largest Ebola epidemic in history. CDC's response to the emergence of Ebola is the largest response in CDC history. The overall goals in an outbreak response are to stop human-to-human transmission and to improve patient care. Stopping human-to-human transmission is characterized by five pillars:

- ❑ Case identification, including isolation and providing care
- ❑ Contact tracing
- ❑ Extensive and effective infection control
- ❑ Safe burials that are sensitive to the population
- ❑ Health communication and social mobilization

Improving patient care incorporates:

- ❑ Triage
- ❑ Experienced and trained staff
- ❑ Strict use of personal protective equipment (PPE), which also prevents transmission

A number of challenges emerged as the Ebola outbreak unfolded. The outbreak essentially moved from the forested region of Guinea toward urban areas first in Monrovia, Liberia, and then to Sierra Leone. The situation is improving in West Africa, as many areas have not seen new cases for 42 days, or two incubation periods. There is a lack of infrastructure in these areas, and the public health and healthcare systems are overburdened. Further, there was a lack of acceptance of Ebola, fear and stigma, and distrust of outsiders. There are immediate and long-term challenges associated with international responses. The immediate challenges pertaining to Ebola and to all of GHS are finding cases, responding to cases, and preventing cases. Long-term aspects of the response follow the GHS model to detect threats early, respond effectively, and prevent avoidable catastrophes.

The international response to Ebola has included over 1000 deployments of public health experts to Guinea, Liberia, and Sierra Leone; training of 765 Master Trainers and 23,000 front-line healthcare staff; more than 400 facility assessments; and laboratory staffing. The Ebola response has resulted in exponential decreases in Liberia and then in Sierra Leone. Ebola had not previously emerged in urban areas, and when it did during this outbreak, there was rapid and significant transmission. The epidemiologic curves in Liberia and Sierra Leone are similar, while the epidemiology looks different in Guinea, where the transmission has been at a relatively low, almost endemic, level. Approaches in Guinea may need to be different, as those populations have not experienced rapid transmission in urban settings.

The domestic response to Ebola was monumental and included the following:

- ❑ Online training of over 840,000 healthcare workers

- In-person training of 6500 healthcare workers
- Designation of 55 Ebola Treatment Centers in 17 states and the District of Columbia
- Visitation of 81 facilities in 21 states and the District of Columbia by Rapid Ebola Preparedness (REP) Teams
- Approval of 56 Laboratory Response Network (LRN) laboratories to test for Ebola (the first Ebola test took 24 hours, while the current tests take four to six hours)

REP teams have been assembled in order to identify how ready facilities are to receive patients who might have Ebola. The CDC Ebola Response Teams (CERT) are trained and ready to assist settings where Ebola patients might be. Additionally, Infection Control Assessment Response (ICAR) visits are designed to evaluate hospitals regarding their preparedness to care for patients.

The Division of Global Migration and Quarantine (DGMQ) in the Center for Global Health (CGH) participated in CDC's EOC to coordinate entry screening and follow-up of travelers to the US from Ebola-affected areas. This work represents a collaboration among CDC, state health departments, the Department of Homeland Security (DHS), the US State Department, and other entities. Enhanced entry screening was instituted at five US airports. Travelers coming from the affected areas are placed into risk categories based on exposure that they might have had, and they are monitored by state or local health departments. Travelers are provided with Check and Report Ebola (CARE) kits, which include information on Ebola, tools to help them monitor themselves for symptoms for 21 days, and means for responding with their information. If the travelers do not respond, then state health departments follow up with them.

As the response to Ebola progresses toward the goal of getting to zero, the priorities shift to providing targeted, technical, thorough epidemiologic contact with community efforts. As the numbers of cases decrease, the efforts increase in intensity. The five priorities for getting to zero are to:

- Reinforce existing incident management and response leadership in most-affected areas
- Strengthen programmatic and operational capacity in most-affected areas
- Expand and improve case detection and management capacity, including Ebola treatment, rapid response capacity, and laboratory testing
- Improve efforts to appropriately engage communities in efforts to reach zero cases
- Continue to innovate and adapt response as needs change

Important innovations are emerging from the Ebola response. These innovations include rapid diagnostics, such as the Biofire, a PCR device that can run on a generator and can provide sensitive results very quickly. The ZMapp trial, which can be used for individuals who have been exposed to Ebola or who are ill with Ebola, is progressing. The trial is occurring in partnership with many organizations, including Ministries of Health (MOHs). Vaccine trials are underway in Liberia, Guinea, and Sierra Leone.

Discussion Points

Dr. Goldman commented that faculty members at her institution travel to West Africa. The individuals live in different states, and the state health departments are to be commended for aligning their guidelines. Three countries are currently listed as having "widespread transmission" of Ebola, and that classification has enormous impact on state and local health agencies and on employers. She wondered when the countries' status may change.

Ms. Villar answered that discussions on that subject are ongoing, and a recommendation has not been finalized. ACD can provide a wider perspective on the impacts and issues associated with those classifications.

Dr. Jernigan said that the goal is for a country not to have cases for 42 days, or two incubation periods, before the current requirements for monitoring are removed. That timeframe is consistent with WHO guidelines. It might be possible to divide the time so that the monitoring requirements are dropped to a lesser level after one incubation period. Some partners feel that direct, active monitoring should continue for 42 days. That approach may be operationally easier due to the amount of time it would take to implement a step-down approach. As monitoring requirements change, there will also be changes to the travel health alert notices.

Dr. Goldman understood that a step-down approach would necessitate another bureaucratic policy. Ending monitoring after 42 days makes sense.

Dr. Jernigan said that 42 days is likely to be the period for Liberia. Sierra Leone and Guinea may have a step-down approach after 21 days.

Dr. Iton commented on the lack of infrastructure in West Africa and in other places where the outbreaks occurred. He wondered about the level of sophistication of quantitatively ascertaining the nature of those deficits. Infrastructure is made up of multiple components and individuals who need skills, equipment, laboratory support, and financial support. He also wondered how to communicate the criticality of infrastructure and what needs to be built in order to get from where we are to where we need to be.

Dr. Jernigan replied that the lack of infrastructure in these areas was known before Ebola. The Ebola response required response from NGOs and governmental organizations, so there is now a better understanding of what is and is not working in the three affected countries and in the countries around them. The current focus is on "getting to zero," and then a recovery phase will be planned, including assessing needs over multiple years in coordination with all of the partners and MOHs. The public health infrastructure in these countries was poorly managed before Ebola, but it is important to utilize opportunities to improve the systems.

Dr. Iton asked about differences among the three affected countries regarding their baseline infrastructure.

Dr. Jernigan said that each of the three countries has historic connections: Liberia to the US, Sierra Leone to the United Kingdom (UK), and Guinea to France. Ongoing connections with the US and UK have made some work easier in Liberia and Sierra Leone, but the connections with France have not been as strong, and it has been historically challenging for outside groups to work in Guinea. However, Guinea has an actively functioning public health system, where the other two countries were inundated by Ebola. Hospitals and clinics closed, and people did not want to go to clinical facilities. Guinea's system is more of a communal approach, and it was able to continue. It may be easier to build on Guinea's existing system. The three countries are

different culturally and linguistically, and there are tribes within the countries that have commonalities and differences. The solutions may not be country-specific, but regional.

Ms. Villar added that Guinea seemed to have a workforce, but it was a challenge to ensure that they were paid. The other two countries did not have a workforce, so personnel were brought in or trained. Responses were quicker in countries where CDC or the US government had a presence. For instance, the Nigerian response was quicker because of CDC's presence and relationships built through the President's Emergency Plan for AIDS Relief (PEPFAR) and other work.

Dr. Richardson noted that the Ebola response is having a continuing impact not only at CDC and in public health sectors, but also in academia and healthcare. Continued guidance is needed for training and maintenance of readiness without becoming burdensome. For some time, there was a ban on students or trainees participating in the care of Ebola patients. She expressed her hope that messages could be shared to ameliorate the paranoia and hysteria that have affected some sectors.

Global Health Security

Dr. Tom Kenyon (Director, Center for Global Health) provided ACD with information regarding the GHSA. The US Congress approved an emergency funding request in December 2014, and implementation of elements of the GHSA has proceeded rapidly. CDC is working as quickly as possible to place teams and resources, and to contextualize GHS with MOHs.

GHS crosswalks tightly with the International Health Regulations (IHR), and the GHSA focuses on accelerating compliance with IHR. GHS is a whole-agency, "One CDC" approach both domestically and in the field. Country plans are anticipated by the end of May 2015, and they will then undergo an inter-agency approval process. In the meantime, CDC is responding to emergencies and continuing work to put systems in place in Ebola-affected countries. The GHSA planning process will help formalize this work.

President Obama hosted more than 40 nations on September 26, 2014, to highlight the GHSA. The event had been planned for some time, but the emergence of Ebola illustrated further the importance of the work. The GHSA focuses on mobilizing other nations to do their part to realize the IHR. Each nation contributes to the Action Packages in its own way. The 40-nation meeting included presentations from the US Secretaries of State, Defense, and Health and Human Services, in addition to the National Security Advisor. That model of a multi-sectoral approach to complex issues that affect all sectors was helpful in Ebola-affected countries.

The GHSA includes 12 comprehensive, measurable targets with specific goals. For instance, one of the immunization goals is to achieve 90% coverage for the measles vaccine. The intent is to achieve all of the targets in the Phase One countries. This work must take place with other partners and entities, such as the United States Agency for International Development (USAID) and DoD. CDC is focusing on surveillance; laboratory capacity; the public health workforce, particularly the Field Epidemiology Training Program (FETP); and EOCs. CDC will participate in other components of the Action Packages and target areas, but the above areas represent CDC's comparative advantage and experience in providing leadership and support in countries. Different US agencies are leading different aspects of the GHS work. For instance, DoD is leading biosecurity work, and USAID is leading in zoonotics. The response is "whole government," not just CDC.

Several elements of the GHSA apply to the Ebola outbreak, including prevention, detection, and response. The GHSA can be used as a framework for planning, communication, and evaluation. Approximately two-thirds of the FY 2015 Emergency Appropriation is devoted to global work. Countries have planning levels so that they can budget according to the targets and Action Packages. CDC is one of many players in this area, particularly after Ebola as other partners such as the World Bank and the African Development Bank are making investments. It is critical for this work to occur at the country level not only so that GHS is socialized with MOHs and part of their priorities and opportunities, but also to leverage resources with other partners.

GHS work fits into CDC's Global Health Strategy in several ways:

- Health Security: improving GHS
- Health Impact: improving the health and well-being of people around the world
- Health Capacity: building country public health capacity
- Organizational Capacity: maximizing the potential of CDC's global programs to achieve impact

The GHSA also presents opportunities for CDC to improve its own organizational capacity by working across programs and across countries, benefiting from the different inputs and platforms; utilizing common laboratory platforms and a common workforce; and building a specimen transport system with large applicability. There are many examples of synergies across CDC programs and ways to leverage resources to address a host of public health issues. GHS also presents opportunities for CDC to work with other US government agencies and partner organizations, including WHO, financial institutions, foundations, and the private sector. The recognition of the damage that Ebola has caused to local economies has served as a warning regarding the potential problems of future events.

Phase One of GHS implementation includes expansion into several countries in Africa and Asia. The current deployment is 350 staff and the overseas presence will expand by nearly one-fourth. These individuals bring specific expertise and can also help other partners design their investments to develop effective systems. Staff will also work in at-risk, non-GHS countries to build capacity to prevent, detect, and respond. This work is moving quickly and efficiently.

A development related to GHS is the formation of an African CDC. This organization was conceptualized as MOHs and governments have looked to CDC regarding how to establish a public health agency. The African CDC is the first health initiative to be approved by all 54 African heads of state. Ebola has accelerated the need to establish the African CDC. The Coordinating Center will be housed at the African Union (AU) headquarters in Addis Ababa, Ethiopia, and five regional centers will also be established. Nigeria will host the West African center. The locations of the remaining centers will be determined by the regions.

The African CDC will begin with a focus on the GHSA. The most additive work will be the surveillance and response network. Of the 54 African countries, none has met the IHR requirements. African leaders recognize this vulnerability, which Ebola has highlighted. The African CDC will begin by building capacity in this area and could well take on other causes down the road. CDC will provide two long-term, resident advisors and will fund a competitive fellowship for FETP graduates to serve for two years at the African CDC and the regional centers. The ultimate plan is to build resilient health systems. As Ebola subsides, CDC teams are able to look at the long-term to help build pragmatic, longer-term approaches to laboratory capacity, surveillance, workforce development, and emergency response.

Discussion Points

Dr. Iton asked about the basic infrastructure in countries with respect to community health workers and lay health workers, and how they might interface with the epidemiologic capacity that the GHSA will build.

Dr. Kenyon answered that community health and lay health worker structures vary by country. These workers are voluntary and are paid a small incentive in some countries. In Ethiopia, Health Extension Workers are funded as part of the formalized healthcare system, and 35,000 of these workers have been trained. They deliver a package of 16 healthcare interventions. This model has great power for overseeing not only clinical issues, but also public health issues. These workers have been engaged in public health responses, such as maternal mortality. A model of community surveillance officers is in place in some areas. The question now is what post-Ebola structure will be sustainable and reasonable in a given country.

Dr. Bal noted that internationally, high blood pressure causes more deaths than tobacco control. He expressed hope that CDC would bolster its response to environmental health and chronic disease, which affect developing countries significantly and in part due to US industries.

Dr. Kenyon recognized the weakness and noted that there is power in information. Chronic disease has been integrated into the FETP so that those workers can help local MOHs generate the evidence and knowledge base needed to drive local decision-making. They have seen impacts in non-communicable disease (NCD) areas such as accidents and trauma. With this approach, countries drive the response as opposed to program funds driving the response, such as in HIV, malaria, and vaccine-preventable disease.

Dr. Frieden added that the capacities being built can work and respond to a variety issues. Additionally, there is willingness on the part of Congress to allocate funds for overseas issues that could hurt the US. GHS funds will not be used globally for NCDs; however, it can strengthen national capacities that countries can choose to use for NCD work. A new branch within CGH will focus on NCDs.

Dr. Goldman observed that a formal assessment of the public health workforce and educational systems in Africa has not been undertaken. Each country is very different, and it is not well understood whether the public health workforce consists of community health workers, nurses, medical doctors, or others. This assessment is needed, and capacity in public health training is needed. Building the training in Africa is important so that those who are trained, remain there. The Association of Public Health Laboratories (APHL) conducts training in Africa on how to set up public health laboratories. She further noted that environmental health is a significant issue in Africa, as air pollution increases and environmental impacts from flooding and mining, and other issues, increase. An African CDC should embrace these issues, and it will probably require funds from other entities and foundations to build that capacity. A public health system will not be functional if it cannot address smoking, hypertension, environmental hazards, and other public health concerns.

Dr. Kenyon agreed and stressed that retention is a challenge. The model in Ethiopia was created to ensure a primary healthcare structure that would not migrate. PEPFAR has engaged in task shifting as well. Health systems strengthening results in public health systems strengthening. CDC can contribute to professionalizing and elevating the importance of information-gathering and processing to inform decision-making.

Dr. Berns asked about biosafety and biosecurity in the GHS countries.

Dr. Kenyon answered that in some countries, the security consists of a fence and locks and should be more rigorous. Biosafety and biosecurity are examples of areas where sectors beyond the health ministry can be brought into GHS.

Update on Recent Viral Outbreaks: Middle East Respiratory Syndrome (MERS), Enterovirus D68 (EVD68), and Measles

Dr. Anne Schuchat (Director, NCIRD) presented ACD with an update on recent viral outbreaks. Middle East Respiratory Syndrome (MERS) coronavirus (CoV) was first recognized in 2012. It was highly lethal and primarily affected adults, primarily those with underlying conditions. Like Severe Acute Respiratory Syndrome (SARS) before it and Ebola after it, MERS also targets healthcare workers. The virus has exported to a number of countries, including Europe and Asia in the last six months.

MERS has a spring seasonality. 2014 was a peak year that received a great deal of attention, and 2015 has also experienced an increase in the spring, including multiple cases in Saudi Arabia. On May 1, 2014, a case of MERS presented in a community hospital in Indiana. This presentation illustrated the concept that diseases are "just a plane ride away." CDC assisted the county, state, and hospital authorities in Indiana. CDC and partners conducted a tremendous amount of contract tracing in the healthcare worker community and among airplane contacts. There was no spread from that importation or from the other importation that occurred in 2014. CDC provided guidance to healthcare professionals, the public, and to guidance. The guidance was updated in April 2015 with the knowledge that the spring seasonality in the Middle East poses a risk. DGMQ has also been updating messaging to travelers.

Over 500 Americans have been tested for MERS in the US, and only two positive cases were identified in May 2014, when the index of suspicion was raised by the spring seasonality. Another peak occurred in October 2014, perhaps related to the timing of the Hajj or because of increased awareness of travel-associated risks. CDC has continued testing and engaged in other activities, including developing a new laboratory test that was exported to the LRN so that states can conduct their own testing. A team from CDC was on the ground in the Middle East last year and in the spring of this year.

MERS was unknown to the world in 2012. The international politics and dynamics made the response complicated. For instance, Saudi Arabia has had five Ministers of Health in the past 12 months and has undergone many changes in the manner in which public health is addressed. Public health at all levels maintains responsibility for responding to the virus domestically, even when it is not in the news. The responsibilities include detection, prevention, and communication. Substantial technical assistance is needed for outbreaks of unknown viruses, even in wealthy countries and in countries with good health infrastructure.

Enterovirus D68 (EVD68) was detected in the summer of 2014 when clinicians in Illinois and Missouri recognized increases in severe respiratory disease in children, primarily those with underlying conditions prompting admissions to intensive care units (ICUs). Routine testing was not revealing, but EVD68 was eventually identified. There are approximately 100 different kinds of EV, and routine testing cannot discern which type is which.

CDC issued guidance regarding how to test for EVD68 and how to submit specimens for testing. Nationwide, over 1500 specimens were submitted, and approximately 45% of them were positive for EVD68. There were probably millions of cases. The diagnosis did not change clinical management of the situation, but was important for epidemiology. Almost every state

had confirmed cases of EVD68. Of the specimens submitted to CDC, 30% were positive for other known viruses, and no other single virus constituted more than 4% of the results. CDC posted protocols for how to identify EVD68 to the LRN in the fall of 2014, and the final steps of securing permission to share reagents with the LRN are still underway.

A clinical phenomenon was detected in the midst of the respiratory surge, a polio-like syndrome affecting children in different areas of the US. Clinicians in Colorado first recognized it, and a number of states have subsequently identified children who have had focal paralysis or weakness similar to polio. The respiratory specimens from these patients have revealed some with EVD68, but testing of the neurologic specimens, primarily cerebrospinal fluid (CSF), has been negative thus far. There is no proof that the epidemic of acute flaccid myelitis (AFM) is caused by EVD68 or is not associated with it, but the timing of the two were close and they were both national in scope.

Unknown viruses such as MERS and SARS are not the only problems. Many viruses that have existed for some time are “known unknowns.” They can change or are challenging in other ways. Commercial tests for respiratory viruses are nonspecific. They determine Rhinovirus and EV, but not which one. As a reference laboratory, CDC uses the traditional method of a two-step nested PCR to differentiate among the types of EV. This approach is time-consuming and labor-intensive and is not intended for surge testing. Last fall, a group at CDC developed new laboratory assays that would be more specific. The Emergency Use Authorization (EUA) is being finalized so that CDC can share reagents with the states. CDC’s laboratory experience in polio helped address EV. This experience is an example of how CDC’s depth helps the agency address unknown threats. The Advanced Molecular Detection (AMD) initiative at CDC has transformed its laboratories and will begin to transform state laboratories. Modern, complex tools can yield answers, and therefore interventions, more quickly.

2014 experienced a significant increase in measles cases in the US. Over 600 cases were identified, most of which were among an unvaccinated Amish community in Ohio that was not opposed to vaccination, but had not had the tradition of vaccinating prior to the outbreak. Since 2010, more measles importations and higher numbers of cases have been occurring compared with the first decade after measles elimination in 2000. There were 60 importations in 2014, twice the number as the average of the previous decade. A large proportion of the unvaccinated were not vaccinated intentionally, either due to personal beliefs or philosophical reasons as opposed to “falling through the cracks” of the system or not having access to the vaccine.

Some of these trends have continued in 2015. So far, 162 measles cases have been identified. Approximately 70% of those cases are associated with an outbreak that began at Disneyland in Southern California. At least one case has been detected in 18 states and in the District of Columbia. There have been importations from several different places, which serves a reminder that there are 20 million measles cases per year in the world. It is an airplane ride away. Approximately 46% of the 2015 measles cases are unvaccinated, and the vaccination status of 37% is unknown. Of the unvaccinated, 43% had Personal Belief Exemptions and approximately 35% were babies too young to be routinely vaccinated. There has been a clamor for protection of babies who are too young and of children who are not able to be vaccinated due to leukemia or other conditions. Debates in the public arena have focused on requirements for vaccination, personal responsibility to protect others, and personal choice.

Every measles case requires an aggressive public health response. The response usually falls on the local health department and frequently involves state laboratories. CDC has established four regional reference centers for vaccine-preventable diseases because many state laboratories were not testing enough specimens for some of these diseases. The regional centers are committed to rapid turnaround of results so that all states have prompt access to quality information. The 2015 measles outbreak has led to increased immunization activity. There has been a threefold increase in adult measles, mumps, and rubella (MMR) vaccination in the public and private sectors.

The measles outbreaks illustrate that even viral outbreaks of known agents are challenging. The measles virus was eliminated in the US 2000, but it is not eliminated from the world. Clinicians must be astute regarding old diseases as well as new diseases, and public health infrastructure is critical. Global efforts to increase immunization will help with problems in the US with measles and other vaccine-preventable diseases. Clinicians are also important for parental acceptance of vaccines and for sustaining and maintaining social norms around vaccinations. State requirements help keep vaccines the default choice and also help protect communities, but those requirements can be difficult to change. Improved immunization registries and information systems will help address the problems associated with unknown vaccination status. It is not clear whether the adult measles cases are due to adults never being vaccinated, or due to a cohort effect from a group receiving a vaccine some time ago and needing another dose.

There is an unfinished agenda related to infectious disease outbreaks and CDC. Laboratory tests are important for public health and could be made available more quickly, but there are bureaucratic and quality control challenges associated with that need. AMD is important for known and unknown agents and has been helpful in several outbreaks. Public health capacities at state and local levels are important, and the approach of creating regional hubs to which every state has access has been beneficial. The Public Health Associate Program (PHAP) has been an important workforce pipeline and has also been important for outbreak response. The California measles outbreak response needed public health advisors to help with contact tracing and communication support. The immunization infrastructure is more than vaccines and has needs beyond purchasing vaccines. The landscape around vaccines is dynamic, and the interplay between consumers, clinicians, and policymakers is changing. The GHSA offers potential to keep Americans safe everywhere.

ACD's advice is welcome regarding whether CDC's efforts are on track and whether the agency is thinking broadly enough to be prepared for these kinds of problems. Initiatives such as AMD, GHS, laboratory safety and quality, and PHAP are means for improving detection, response, and prevention of viral outbreaks, but there may be other gaps. CDC plays a special role in laboratory response. Clinical and commercial laboratories conduct most of the testing for infectious disease issues. Their goals are focused on diagnosis and treatment, where CDC is interested in "unknowns." State and local laboratories are keeping up with the "knowns" and may not receive the most important specimens. Global laboratories are building their skills, systems, and workforce to be able to test for priority pathogens and syndromes. CDC laboratories are unique in striving for both depth and breadth as well as sustained capacity to address "knowns" and "unknowns."

Discussion Points

Dr. Farley has been worried about state and local laboratories because of budget cuts over the years. Workforce has been another significant problem as quality people retire and are not necessarily replaced. He asked about national-level capacity and what could be done to bolster it. CDC laboratories are strong reference laboratories, but the front-line laboratory system appears to be relatively weak.

Dr. Schuchat said that sustaining the CDC laboratory workforce is also a challenge. Like the states, CDC has had many categorical funding years. The polio laboratory is well-funded and has expertise that can be shared. The influenza laboratory is also well-funded and has provided opportunities to invest in areas such as bioinformatics and whole genome sequencing that can help all infectious disease laboratories. The AMD Initiative, the Laboratory Leadership Service, and the GHSA offer opportunities to ensure that the ability to support state, local, and global partners as they address complex infectious disease threats.

Dr. Bell agreed that modernization is a significant issue for CDC as well as for state and local health departments. There are similar movements in the clinical arena, especially in the bacterial sector, with multiplex platform assays. Funding is an issue, and the infrastructure is somewhat fragile, despite new technologies. A very large proportion of state laboratory funding comes from CDC, so CDC's budget has an impact on them.

Ms. Rosenbaum pointed out that immunization requirements will never be absolute. The recent measles outbreak has brought movement that has not been seen before—a great concern among the peers of families who did not have their children immunized that exposing their children to un-immunized children is not a good idea. This blowback has not been felt in that way before, because the people who are not getting their children immunized tend to be opinion leaders in this area. She wondered how public health can build on this realization as an opportunity for health education.

Dr. Schuchat replied that their communication strategy includes reinforcing social norms. Most people vaccinate their children. It is extreme not to vaccinate children. In this year's outbreak, many people were inconvenienced by the idea that their baby may be restricted because someone else chose not to vaccinate. CDC has upgraded information on the Web with information from the public health law program review of state requirements. State and national coalitions are organizing around this moment. As clinical leaders, the American Academy of Pediatrics (AAP) is working with policymakers. The Immunization Partnership in Texas is also examining policy. The visible outbreak at Disneyland brought vaccines to the consciousness of mainstream America in a new way.

Dr. Palacio raised the opportunity to reach out to other partners to speak not just about the science of vaccines, but also about the art and communication strategy of vaccines. The business sector could be an important partner, especially given how Disney was affected by the measles outbreak. Employers are inconvenienced when parents stay home. Unique partners could galvanize and fund more robust and innovative communication strategies.

Dr. Schuchat said that CDC works with the business and private sectors regarding influenza vaccines. Traditionally, pediatricians, schools, and state coalitions have been partners for infant and toddler vaccination. Working with the private sector in those areas is an interesting opportunity.

Dr. Mullen expressed hope that the states and CDC could work together to share consistent messages regularly. Even in a year in which the influenza vaccine is less effective, the message is that "it's still the best thing you can do," as opposed to, "it doesn't work and it's not worth it." The National Conference of State Legislatures (NCSL) and the National Governors Association (NGA) could be useful partners regarding vaccination and regarding public health laboratories. Policymakers may not be aware of what state public health laboratories do. There may be opportunities there to help build infrastructure and capacity. States may need to coordinate with CDC more closely when new laboratories are built to ensure that the facilities have the appropriate technical specifications.

Dr. Schuchat said that CDC conducts extensive messaging through its partners during influenza season. They are engaging in communication research regarding how to talk about the influenza vaccine. This influenza season saw excess morbidity, particularly in the elderly. It is critical to talk about the vaccine in a way that does not over-hype its effectiveness but also does not underestimate its importance. CDC did community engagement work to learn how to message around vaccines. CDC does work with NCSL and NGA. There have been interesting conversations regarding how CDC should engage, versus states or third parties. Immunization requirements are state issues, and CDC provides the evidence base and technical packages to partners.

Antimicrobial Resistance Update

Dr. Beth Bell (Director, NCEZID) provided ACD with an update on the Antimicrobial Resistance (AR) Initiative at CDC. National momentum on AR has been building for a few years, beginning with the release of the report "Antibiotic Resistance in the United States" in 2013. The report put information in one place in a manner that was understandable and could be communicated to policymakers. The model could be applied in other areas to drive policy. The report addressed the burden of disease and the fact that AR broadly affects the population. For example, successes in cancer therapy are predicated on the assumption that infections can be treated, and the spread of resistant bacteria threatens this success. The report ranked threats into categories: urgent, serious, and concerning.

The report helped to spark broader governmental interest in redoubling efforts to address the problem of AR. The National Strategy for Combating Antibiotic-Resistant Bacteria (CARB) was released on September 18, 2014 and was the result of an intensive process led by the White House to convene all of government to focus on AR. The report was associated with an Executive Order to establish an Advisory Committee. Also in September 2014, the President's Council of Advisors on Science and Technology to Combat Antibiotic Resistance released their report. The priorities listed in that report aligned well with the National Strategy. The National Action Plan for CARB was released in March 2015. The plan includes detailed steps to implement the National Strategy and the recommendations of the Council of Advisors. Significant outcomes are expected by 2020. The activities in the plan are consistent with the President's FY 2016 budget request. A companion TB Action Plan is under development.

The categories in the strategy are as follows:

- Slow the Emergence of Resistant Bacteria and Prevent the Spread of Resistant Infections
- Strengthen National One-Health Surveillance Efforts to Combat Resistance
- Advance Development and Use of Rapid and Innovative Diagnostic Tests for Identification and Characterization of Resistant Bacteria

- Accelerate Basic and Applied Research and Development for New Antibiotics, Other Therapeutics, and Vaccines
- Improve International Collaboration and Capacities for Antibiotic Resistance Prevention, Surveillance, Control, and Antibiotic Research and Development

CDC chiefly focuses on the first two and fifth categories and has also been involved with the others as well.

CDC's AR Solutions Initiative requests $264 million in the President's FY 2016 budget. The initiative has three categories:

- Detection and response, establishing regional laboratories, increasing the number of Emerging Infections Program sites, and strengthening the National Antibiotic Resistance Monitoring System (NARMS)
- Prevention and protection, establishing AR prevention programs in every state and antibiotic stewardship programs in facilities
- Innovation, including prevention research through the Prevention Epi-Centers.

The FY 2016 initiative calls for establishing five to seven regional laboratories. Current capacity in the United States to detect and track resistant bacteria and associated outbreaks is not strong. Clinical laboratories focus on testing that provides information needed to make treatment decisions, and state public health laboratories do not tend to have the expertise or resources to comprehensively or systematically track resistance. CDC serves as a national reference laboratory, but does not have the capacity to comprehensively track resistant bacteria nationally.

NHSN is the nation's largest system for tracking healthcare-associated infections (HAIs). It operates in over 12,000 facilities, each of which can use their facility's information for quality assurance, quality improvement, feedback, and tracking. Information from NHSN has been used by state health departments to identify facilities in states that need additional assistance and for benchmarking within the states. NHSN information is used at the federal level for benchmarking among states and for tracking annual progress regarding HAIs. Planned improvements in NHSN are pivotal to the success of the AR initiative, including electronically capturing laboratory data about resistant organisms; and about antibiotic use from pharmacy records. The modules have been developed and need to be scaled up so that they can be implemented widely and are user-friendly and acceptable to facilities.

The EIP is CDC's gold standard method not only for conducting active surveillance, but also for monitoring the impact of prevention strategies and informing new strategies. The number of EIP sites is proposed to be doubled, which will add to understanding of resistance in subpopulations by increasing the population base. The expansion of EIP also will allow for burden studies to be completed faster and also improve understanding of resistance patterns.

AR is a community problem. It spreads among facilities and in the community, and it must be addressed by meaningful programs at the state and community levels. Additionally, stewardship is crucial, as antibiotic overuse is the major driver of AR. There are some good examples of stewardship programs in facilities, but they are in their infancy. Improving antibiotic use in the community has slightly different issues that also need to be addressed.

Innovation is an important aspect of AR work. There is a great deal of interest in the microbiome from the basic science as well as the public health perspectives. The AR Solutions

Initiative proposes to explore issues relevant to public health by describing the typical microbiome disruption caused by antibiotics and tracking and evaluating how changes in the microbiome affect the attack rates of resistant bacteria. The AR Initiative also will expand preventive research through the Prevention Epicenters.

Some quick "wins" are in progress at CDC with government and community partners. The White House is planning a Stewardship Forum for May 2015. Over 90 partner organizations, including some large health systems, are interested in participating and committing to making progress. CDC is working with FDA on an AR Isolate Library. AMD is being used to further understand transmission patterns, and collaborative efforts are ongoing with NIH and the Broad Institute. Progress is being made on the NHSN Antimicrobial Use and Resistance (AUR) modules in long-term care and in hospital networks.

A challenge associated with this work is sustainable resources. Infection control is a focus of the emergency Ebola funds, and the AR Initiative can build on these accomplishments. The rate of IT adoption is important for tracking and feedback from the AU and AR modules within NHSN. There are opportunities associated with interest in, and commitment to, stewardship among different sectors. Other opportunities are associated with core state infrastructure with expertise in healthcare that can adapt to other issues and public health threats. A number of initiatives are focusing on developing new antibiotics, and the AR Initiative infrastructure will provide opportunities to monitor their use.

Discussion Points

Dr. Benjamin commented that AR presents an excellent opportunity to bridge public health and medical care. There are crosswalks among disease surveillance and prevention. He hoped that work would take place within the framework of public health and medical care collaboration.

Dr. Goldman agreed and noted that the One Health perspective will be important, especially given that many of these antibiotics are used in animal care and animal husbandry. The work with FDA and USDA is commendable. She suggested also working with the Environmental Protection Agency (EPA). She recalled past problems associated with the antimicrobial products on the market.

Dr. Bell said that the US government agencies have worked well in the One Health approach. There is interest in improving surveillance and in being able to measure farm-based antibiotic use in a meaningful way. There are opportunities to better understand the impacts of antibiotic use and to monitor changes that will occur as FDA guidelines are implemented. CDC has had some discussions with EPA as well.

Dr. Richardson applauded the AR Initiative and offered a word of caution not to underestimate the challenge that is represented by the ingrained prescribing practices among physicians. The problem and solutions are clear, but the culture is so ingrained that approaches such as marketing, decision support, feedback, and other tools associated with electronic health records (EHRs) will be needed.

Dr. Bell agreed and added that NCIRD has done work in the past to improve prescribing practices by better understanding variations in prescribing practices, reaching the local level to understand what drives variations in the frequency of antibiotic prescriptions across the country. This problem can be approached from a health systems perspective as well. The role of the consumer can be important also. The social norms regarding HAIs are changing, and

consumers are asking how HAIs are being prevented in healthcare facilities. In similar fashion, if consumers change the way they think about antibiotics, the landscape may change.

Dr. Frieden commented on the issue of over-treating symptoms and under-treating causes. These issues affect both antibiotic prescription and the overuse of prescription opioids. There may be a lack of recognition of risks and benefits, perhaps driven by marketing; however, many of the over-utilized products are generics. The marketing works because it addresses symptoms. A great challenge is to address symptoms adequately while also addressing causes creating the need for treatment. This problem is broad.

Dr. Greenberg commended Dr. Bell and the center for raising consciousness in the US on these issues.

Letter of Service Presentations to ACD Members Rotating Off on June 30, 2015
Dr. Frieden expressed appreciation for the time and energy that ACD members devote to helping CDC serve the public better. ACD is a significant part of CDC's success and progress. He emphasized that the ACD subcommittees and workgroups make strong contributions and thanked ACD members for their participation on them. He thanked the following ACD members who were rotating off of the committee and presented them each with a certificate:

- Dr. Georges Benjamin
- Dr. Nisha Botchwey
- Dr. Herminia Palacio
- Dr. Alan Greenberg

Ethical Considerations for Public Private Partnerships
Ms. Becky Payne (Deputy Chief of Staff, Office of the Director) addressed the ACD regarding CDC's public and private partnerships. CDC has many relationships with various partners, including businesses, philanthropies, and individuals. The agency has financial relationships as it makes purchases and contracts with companies. CDC also receives funding through the CDC Foundation. The agency recognizes that its activities shape the marketplace through its research and evaluation, as well as its guidelines and recommendations. CDC also participates in advancing technology, including technology transfer and research and development. The agency innovates in the public sphere and then works to transfer those innovations to the private sphere, where the technology is expanded and reaches a broader audience. There are informal interactions with partners as well at professional meetings and to serve as a consultative resource. CDC also seeks important advice and consultation from partners. In addition, CDC experts interact with experts in the private sector on external committees, workgroups, and coalitions. Depending upon the nature of the external body, there is mixed guidance for federal employees regarding limitations and boundaries for their interactions.

CDC has a policy for accepting gifts from outside entities, which are not limited to the private sector. The policy includes some guidance regarding conflicts of interest. CDC has the authority to receive gifts directly, although most gifts come through the CDC Foundation. Another formal policy is the Standards of Ethical Conduct for Employees of the Executive Branch, which is directed toward individual staff members' personal financial holdings. Neither policy provides guidance regarding organizational conflict of interest, however.

Informal benchmarks and guiding principles for public private partnerships have been created. The gap in formal guidance has led some individual centers to create their own informal guidelines, which are varied. The variation is challenging and should be clarified so that staff

can do the work that they need to do in partnership with outside entities. CDC has an internal Public Health Ethics Committee (PHEC) that is available for consultation.

CDC values its partnerships and has attempted to implement internal supports for entering into partnerships, evaluating the strategic value of a potential partner, considering the feasibility of executing a partnership, and impact. Education is also provided regarding conflict of interest. It is important to understand the perspective of private sector parties related to public health and the potential impact that a partnership can have for them. The Guiding Principles also provide guidance regarding how to engage with partners, including when to continue and when to pull back.

In July 2014, a trend of increasing funding for a particular program at CDC was noted. An internal review of the program was conducted to assess three aspects of the situation, which included:

- ❑ Determining CDC's involvement in the development of treatment guidelines.
- ❑ Examining the coalition that was separate from CDC, but that worked closely with CDC, and included representation from the pharma and diagnostic industry.
- ❑ Considering CDC's relationships associated with the communication campaign to increase testing and awareness of new treatment availability.

The recommendations from the internal review noted that more oversight could be conducted within the Office of the Director. Specifically, the conflict of interest review needs to be strengthened. In this case, the internal review recommended restricting for-profit gifts to only those with no real or perceived conflict. In some situations, subject matter experts (SMEs) from CDC sat on and participated on a guideline-setting body. Their roles were adjusted to be non-voting members. None of these issues is addressed clearly in CDC guidelines or policy for individuals or for the agency as a whole.

A Conflict of Interest Review has always been a requirement of CDC's gift policy, but the administration of the review is left to the discretion of the centers for gifts below a $2 million threshold. The checklist for conducting the review lacked concrete guidance. Beyond the current policy, a panel of six representing a range of experience within the agency meets monthly as the Conflict of Interest Review Panel. The panel receives advance submission of background information on proposed projects and proposed donors. The Principal Investigator (PI) makes a presentation to the panel. The panel members meet in a closed session to discuss their concerns. The panel has expanded to review gifts from all donors, not just from the CDC Foundation.

Another CDC program experienced a dramatic increase in the number of gifts from August to December of 2014. In that period, 21 gifts came before the panel to support 13 projects within the program. Of the gifts, 65% were proposed from two companies that manufacture two new treatments. Eleven of the gifts were submitted in December. No single element of the situation was wrong, but as stewards of the agency's reputation, it was determined that outside consultation and guidance was needed.

Firewalls are not explicit regarding interaction with funders. These interactions take place informally and are not spelled out in policy. There may be perception in the public domain regarding whether there is influence and long-term gain for companies that participate in these studies. The internal mechanisms have been strengthened to be responsive to situations as they arise, but transparency is critical in this arena, and the time has come for an external review to help clarify and answer the following questions:

- ❑ What constitutes an organizational conflict of interest?
- ❑ What practices should be in place for staff who are operating with gift funds? Many disclosures focus on funds coming directly to CDC, but the disclosure is not clear when the funds sit in a third-party arrangement. What access should be granted to interim data for funders who provide funding for ongoing or cohort studies? What are the roles of CDC Principal Investigators and CDC Foundation Program Officers?
- ❑ What guidance is needed for programs about accepting gifts from foundations tied to for-profit companies? The role of industry representatives participating in coalitions? Is there a funding limit?

An ACD workgroup is requested to provide outside input on these questions and to:

- ❑ Conduct a review of current guidelines, policies and practices
- ❑ Establish benchmarks against other federal agencies and academic institutions
- ❑ Provide recommendations to inform ongoing policy and process improvements
- ❑ Conduct a conflict of interest review
- ❑ Provide recommendations about CDC staff interactions with industry partners
- ❑ Provide guidance about implementation of programs funded by industry partners

CDC's work with private partners makes much of its work possible, and the agency needs clarity, good guidance, and support for its staff.

Discussion Points

Dr. Iton asked about the earmarking of gifts. It is important to determine whether a gift is being given so that the giver will receive some benefit. The gift should be separated from the benefit by as many independent decision-makers as possible to reduce the *quid pro quo* effect. He wondered about a mechanism by which gifts can be accepted, but cannot be earmarked.

Ms. Payne said that the policy describes that a donor can indicate a preference for a gift but is not allowed to dictate how the gift is used. CDC honors the spirit in which a gift is intended in broad ways, but the specific use of a gift is tied to the pre-established priorities of a program. The process is similar with the CDC Foundation, in which concepts are developed and proposed by CDC internal staff, approved, and then the CDC Foundation seeks funding to support the work, not the other way around. There are gray areas, and CDC's legal staff ensure that the agency is on the right side of *quid pro quo*, but public perception and reputational risk are important factors.

Dr. Farley appreciated that CDC is addressing these issues now, as potential problems are likely arise in the future. Establishing benchmarks against other situations and agencies may not be helpful, as CDC is unique in its capacity as a recommendation-providing agency rather than a regulatory agency, and there may not be useful comparisons available. He is not comfortable with some of the policies adopted by other government agencies. Regarding a general philosophy, it is likely to be better to err on the side of not accepting gifts that may carry

a perception of conflict. These decisions are difficult, but the long-term institutional risks can be large.

Mr. Charlie Stokes, President and CEO of the CDC Foundation, greeted ACD and noted that most of the funds that come to CDC from outside come through the foundation. They have thought about these issues from the beginning of the foundation. Most of the gifts in the first 10 years of the foundation were from other foundations. Over time, the funding sources have evolved and now include major funding from corporations and for-profit entities. An ethics expert was consulted to help the foundation understand the questions that they should be asking of potential funders. The questions include: Whose idea was this? Is it CDC's? Is a funder open to other funders being involved? Will the funder receive early access to information? This series of "red flag" questions have been incorporated into the process of accepting every gift. Total gifts have increased over the last 10 years. This year, the foundation supports approximately 270 individual programs at CDC and will raise an excess of $100 million for those gifts. The funding supports CDC priorities. Approximately 20% of the CDC Foundation funding currently comes from for-profit organizations, much of them from pharma. The foundation believes that its process is ethically sound, but in this age of transparency, the foundation and its board realize that "optics is just as important as ethics." There is an art associated with the ethics of accepting gifts from one organization and not another. He appreciated ACD's help with these issues so that as the foundation continues to grow, everything it does only helps CDC.

Dr. Benjamin pointed out that while CDC is not a regulatory agency, when CDC speaks, people listen. The agency's reputation may have more impact than a regulatory agency, and that brand must be protected. Part of this discussion should include a determination of the absolutes from which CDC will not accept money. Those absolutes likely include tobacco, alcohol, and firearms. All others are probably "on the table," and alcohol may even be somewhat "fuzzy." The issue of optics is critical, as is the issue of undue influence. Transparency is essential so that Congress and the public have access to the process and information and there is no sense that things are done in secret. He disagreed with the notion that CDC may not rely on benchmarks utilized by other agencies, because CDC should not position itself as an outlier. Congress has crafted a process by which the FDA receives money from industry via the Reagan-Udall Foundation. The funds from the foundation allow for the receipt of funds that may not support FDA's regulatory mission, but will support its mission pertaining to regulatory science. CDC should be viewed by a reasonable person as having done reasonable due diligence in a transparent manner. The agency should be able to explain clearly the cost-benefit to the country's well-being associated with any gift and why a gift does not represent undue influence. He encouraged CDC not to overthink these issues, because scandal can erupt at any moment depending on timing, context, and motives. He hoped that CDC would not become paralyzed by the analysis of these issues such that it is unable to act in a timely manner.

Dr. Palacio said that a main issue that her foundation asks is: Is the main issue a charitable public health purpose? If there is benefit to the donor, is it an incidental benefit? These questions are not black and white, but provide a lens for considering potential gifts. Regarding benchmarking against other agencies, CDC's reputational risk is critically important because CDC is not regulatory. Its power rests in compelling people because it is a trusted entity. She suggested gleaning lessons learned from scandals and problems at other agencies in order to think about, and avoid, unintended consequences.

Dr. Goldman thought that the approach to accepting gifts seems solid. It is also complicated, and she wondered why a minimum level was not established for a potential gift to go through the process, given that it takes a great deal of staff time. The questions that the agency is asking are good ones. She noted that CDC staff should interact with partners and participate on external committees. It is worthwhile to insist that other stakeholders and consumers also participate on those committees, regardless of whether a gift is being received, especially if the interactions are repeated and CDC is only hearing from industry partners. Every part of CDC is not involved in writing guidance, but some parts of the agency do have an enormous impact on industry through guidance, such as the immunization program. Nobody involved with that program should be associated with gifts that come from vaccine-related companies. She suggested identifying the people at CDC who prepare guidances and ensuring that their work is spotless.

Dr. Greenberg asked whether CDC has reached out to its sister agencies within the US Department of Health and Human Services (HHS) regarding these issues.

Ms. Payne said that CDC has informally identified relevant individuals at sister agencies and reached out to them. The CDC's Chief of Staff Office has a small unit that focuses on business partnerships and oversees the grant mechanism by which CDC provides funding to the foundation. There is no universal structure for this work in other HHS agencies, so they are in the process of identifying where the work takes place. She has met with personnel from the new FDA foundation, and they are in the process of bridging those connections and understanding their internal policies, understanding that the information represents one sector's perspective. The decisions that CDC makes and the policies and procedures that it follows impact its partners, so the input of an external group will help identify what the agency should do.

Dr. Greenberg agreed and noted that it may be useful to work with HHS and "manage up," given that CDC is part of HHS.

Dr. Mermin reflected on the question: What is "clean money?" Certain industries are antagonistic to public health, so it would not be appropriate to receive gifts from them. They have not discussed issues associated with individuals who might receive funds from those industries or from other means. Another difficulty in public health is when its goals are aligned with potential funding industries. What happens if CDC is interested in implementing screening recommendations, and a company produces a diagnostic test or a treatment for the illness to be diagnosed by the screening? Drawing that line is quite difficult. They must also ask when they are implementing a Type 2 error. That is, when are resources turned down because it is easier to say "no," but there will be implications for the lives of Americans as a result?

Dr. Frieden thought that it would be helpful to assemble a subset of individuals to work on these questions as a workgroup. He offered an example of a gift that has become controversial. CDC accepted money from sugar producers in Central America to study kidney disease. There would have been no other way to conduct that study otherwise, but it is possible that sugar producers are contributing to kidney disease. The funders were willing to leave the evaluation design up to CDC, so it was deemed appropriate. However, it is advisable to avoid impropriety and the appearance of impropriety. These lines are not easy to define.

Dr. Bal suggested that CDC is practically sacred in public health. The concept may be romantic, but he hoped that the agency would not be sullied for any reason, even if money were "left on the table." For some, working with CDC gives them an "innocence by association" label without co-branding. The CDC Foundation's process is thorough and takes a broad perspective, but he hoped that CDC would not fall victim to a ripple effect from working with the private sector.

The following ACD members indicated their willingness to participate on an ethics-focused workgroup: Dr. Farley, Dr. Richardson, Dr. Bal, and Dr. Iton.

Health Disparities Subcommittee Update and Discussion
Dr. Lynne D. Richardson (Health Disparities Subcommittee Chair) introduced herself and shared with the ACD a progress update on the "CDC Advisory Committee to the Director Health Disparities Subcommittee Recommendations for Achieving Health Equity," which the Health Disparities Subcommittee (HDS) issued in 2014.

The HDS membership includes individuals from a range of interests, including state and local health, academia, and foundations, and a broad spectrum of minority groups. The group generated, and ACD approved, six recommendations for CDC which are to:

- Develop a CDC framework for action to achieve health equity
- Identify and monitor indicators of health equity
- Align universal interventions that promote better public health with more targeted, culturally tailored interventions in communities at highest risk to reduce health disparities and achieve health equity
- Support the rigorous evaluation of both universal and targeted interventions and, where indicated, the use of culturally appropriate evaluation strategies, to establish best practice approaches to reduce health disparities and achieve health equity
- Build community capacity to implement, evaluate, and sustain programs and policies that promote health equity, especially in communities at highest risk
- Support training and professional development of the public health workforce to address health equity

It is important to keep these recommendations in the front of minds of the ACD and CDC leadership so that health equity is a fundamental way of viewing every aspect of how public health is practiced.

The first recommendation on developing a framework for action has been operationalized through the annual State of Health Equity Forum at CDC. These events have focused on four areas associated with the framework:

- Monitoring and measurement
- Programs
- Policies
- Infrastructure

This year's forum focused on presenting best practices regarding evidence-based programs and practices that move health equity forward. The 2015 forum will focus on policy and the intersectoral collaborations that are critical for addressing the root causes of disparities. The framework for action is being compiled and will be featured in a special supplement to the

Journal of Public Health Management and Practice (*JPHMP*) in early 2016. The supplement will highlight some of the most successful aspects of building a centralized framework.

The recommendation to develop health equity indicators represents difficult work. HDS has joined with the State, Tribal, Local, and Territorial (STLT) Subcommittee to recommend that this work include a consideration of social determinants of health (SDOH) and non-health data sources to understand how to monitor health equity and how to monitor the agency's progress toward its health equity goals. CDC is in the process of developing a strategy to routinely monitor structural and SDOH to understand health equity at a national level. This work has begun with an assessment of the Healthy People (HP) framework to find indicators for SDOH that can be built to monitor health disparities. This undertaking is long-term, and CDC is taking it seriously.

Regarding the recommendation pertaining to workforce training, CDC already had several efforts underway. The efforts to continue and grow those efforts are clear.

Dr. Richardson expressed her hope that the work would continue to spread and that each of CDC's centers, institutes, and offices (CIOs) would embrace the recommendations and internalize them into their activities. She encouraged ACD members to join HDS.

Discussion Points

Dr. Greenberg commended Dr. Richardson and HDS on not only the creation of the sweeping recommendations, but also on the progress that has been made on them.

STLT Subcommittee Update

Dr. David Fleming (STLT Subcommittee Chair) noted that the STLT Subcommittee operates with three ongoing Think Tanks:

- ❑ Public Health Surveillance
- ❑ Public Health Finance
- ❑ Social Determinants of Health

The group is formulating another think tank focused on the quality and sustainability of CDC's PHAP. They will develop proposals through the STLT Subcommittee to be presented during the October ACD meeting.

Time restraints prevented a full report from the social determinants of health (SDOH) think tank, but work remains robust and reflects strong coordination among cross-cutting CDC offices and three groups of the ACD. Of note is development of one web portal that organizes current CDC efforts across the agency related to SDOH with an aim to go live by the end of the summer.

The Public Health Surveillance Think Tank has focused on new Congressional language in CDC's budget asking CDC to work with state and local officials to create an agile, cloud-based, flexible IT platform. Partners such as the Council of State and Territorial Epidemiologists (CSTE) agree that there have been been longstanding issues with CDC surveillance reliance on independent, legacy systems. There is a great deal of duplication in the system as well as inefficiency.

Dr. Fleming asked ACD to endorse the following proposal from the STLT Subcommittee:

"Formally endorse an approach that would decrease surveillance systems, requested data from States, and duplicative information channels. Toward that end, CDC should:

- ❑ Transition from many silo'ed surveillance systems to fewer multifunctional systems by:
- ❑ developing a policy on discontinuing duplicative, redundant surveillance systems; and
- ❑ creating a review process for programs that wish to create an individual, silo'ed surveillance system.
- ❑ Work with public health departments to develop a cloud-based and flexible IT platform to improve public health surveillance."

Motion

Dr. Richardson moved to endorse the proposal from the STLT Subcommittee. Dr. Bal seconded the motion. The motion carried unanimously with no abstentions.

Dr. Chesley Richards thanked the ACD and the STLT Subcommittee and its Think Tanks. There has already been good energy between the CIOs at CDC to work toward these goals to be responsive to Congress and to CDC's partners.

Dr. Fleming explained that the Public Health Finance Think Tank of the STLT Subcommittee has been doing a great deal of work pertaining to improving the efficiency and effectiveness of the Preventive Health and Health Services Block Grant, including ways to measure progress. The group is also working on ways to define and attach costs to foundational capabilities at the state and local levels. The President's Budget for 2016 includes a line item specifically for building foundational capabilities.

Global Work Group Update and Discussion

Dr. David Fleming (Global Work Group Chair) said that the Global Work Group (GWG) had met the day before and discussed many topics that had been discussed by the ACD that morning. Dr. Palacio and Dr. Greenberg are two GWG members who are rotating off of the ACD, so it will be necessary to supplement that group with additional ACD members. Dr. Farley, Ms. Rosenbaum, and Dr. Bal have expressed interest in participating on the workgroup before. Anyone who is interested should inform CDC leadership.

Important initiatives are ongoing in global health. Polio eradication is moving forward, and it appears that polio has been eliminated from Nigeria. CDC is also embarking on an exciting project to eliminate malaria in Haiti by 2020. The funding that has been made available for GHS is designed to build capability. Capability costs are ongoing, however, and GWG discussed the importance of using the current funding responsibly while thinking about strategies to assure some continuation of funding after the allocation ends. Three specific recommendations on this front were to:

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- ❑ Look critically at the many categorical funding streams that apply to global health and determine whether some of those funds can be used for these capabilities on an ongoing basis.
- ❑ Borrow a lesson from foundational capability work in the US—the way to get funding is to define what is needed and to cost it.

- ❑ Socialize these efforts. The most effective advocates for these resources are people within countries. Engage MOHs and political leaders to define and own the importance of these capabilities and the costs of maintaining them.

Discussion Points

Dr. Frieden pointed out that the Ebola response and GHS initiative have provided opportunities for CDC to forge new relationships with other parts of the US government. The area remains challenging, however, and he hoped that the GWG could provide advice on it in the future.

Dr. Greenberg commented that new members of the ACD would receive a manual of policies and procedures of the committee, including a list of all the workgroups and who serves on which. It is expected that each ACD member will serve on one or two workgroups or subcommittees. Much of ACD's work is accomplished in these small groups.

CDC Progress on Laboratory Safety Improvements

Dr. Leslie Dauphin (Interim Lead, Laboratory Safety) provided ACD with updates on CDC's progress in responding to the recommendations from the ACD, as well as progress on additional laboratory safety improvements that were initiated as part of CDC's internal review. CDC's laboratory staff are dedicated to safety. This work is important to the agency and its staff. The process will be continuous, and CDC will continue to seek opportunities where they are appropriate.

In July 2014, in response to laboratory incidents, CDC imposed a moratorium on the transfer of biological material out of biosafety level (BSL)-3 and BSL-4 laboratories until processes were reviewed and improved. The moratorium provided an opportunity for the agency to review all of its laboratory practices and policies and to identify opportunities for improvement. The process included a review of all laboratory practices in all of CDC's BSL-3 and BSL-4 laboratories. An internal Laboratory Safety Improvement Workgroup (LSIW) was created, comprised of experts in laboratory safety, policy, and other areas from across the agency. The group additionally met with stakeholders within the agency to ask for recommendations regarding how to improve procedures.

The review showed that CDC laboratories have solid practices in place and provided an opportunity to share and harmonize practices across laboratories. There were areas for improvement, however. One of the instituted changes was the implementation of checklists for critical steps in protocols for inactivation of pathogens. Procedures were also applied for contamination control, segregation of materials, and additional safeguards, such as camera systems in high-containment laboratories. The camera systems were initially not well-received, but they are a viable alternative to having two people in a laboratory. The systems are working well. They are used to record critical steps of procedures. The supervisor can review the steps to ensure that they were performed correctly and approve the transfer of materials. The moratorium for 52 of the BSL-3 and BSL-4 laboratories was resolved in October 2014.

In September 2014, CDC completed a "Clean Sweep" of all of its facilities on all of its campuses. This process included a review of over 1000 rooms to identify biological select agents and toxins in non-secure places.

In January 2015, disinfection procedures were standardized across CDC's infectious diseases laboratories, and procedures for custodianship of specimens were enhanced in February 2015. March 2015 saw the rollout of a new electronic specimen inventory management system. The initial rollout was to CDC's infectious disease laboratories at the Atlanta campus, and rollouts to

additional facilities will occur soon. More than 200 staff have been trained on this system. CDC also completed a self-initiated biological specimens inventory, which exceeded the requirements of the Clean Sweep. The inventory comprised a box-by-box and vial-by-vial inventory of more than 7 million samples in long-term storage. On April 1, 2015, CDC updated the Select Agent Incident Response Plan to include specific, standardized decontamination procedures in the event of a release.

LSIW conducted 13 staff engagement sessions on laboratory safety-related topics. The responses were compiled into a report that informed the internal group's recommendations to Dr. Frieden regarding improving laboratory safety. Additionally, a Laboratory Consultation Program was piloted in two laboratories. This program is designed to be a peer-to-peer consultation rather than a regulatory review.

ACD's recommendations to CDC regarding laboratory safety are aligned with the results of the internal review. The recommendations are divided into seven categories:

Leadership:

- ❑ Funding for laboratory safety programs and laboratory safety training should be established from a central funding source and should be considered a fundamental mission for the CDC.
- ❑ Create a position for a biomedical scientist in the Director's office to lead this (*laboratory safety programs*) effort.

Governance:

- ❑ Establish governance structures that provide accountability and oversight authority to a central entity for laboratory safety and compliance committees with ultimate authority at the level of the Office of the Director.

Risk Assessments:

- ❑ Broaden the scope of the Institutional Biosafety Committee (IBC) to include work with pathogenic microorganisms and biological toxins or establish a centralized, standardized mechanism for consistent and thorough review and risk assessment of proposed research activities.
- ❑ Risk assessments should be performed for experimental work being done at CDC. The benefits and risks of proposed experimental work should be documented before the work is undertaken.

Laboratory Safety Training:

- ❑ Establish a standardized lab safety training curriculum across CDC with standardized methods for competency skills mapping and refresher training.
- ❑ Establish a fellowship/internship program to train scientists to serve as laboratory safety professionals who serve as liaisons between the labs and the Environment, Safety, and Health Compliance Office (ESHCO) or other central lab safety entity.
- ❑ Responsibilities and facilities for lab safety training should be in-house.

Culture of Safety/Incident Reporting:

- ❑ Efforts to establish a culture of *responsible science and accountability* are of critical importance. This culture of responsible science will require prompt and accurate reporting of incidents or breaches in standard protocol without fear of reprimand or punishment.

- Reporting is important for facilitating the analysis of incidents and the establishment of corrective actions to mitigate repeat occurrences. Lessons learned from these activities should be shared with the community.
- In this culture of safety response, ensure that scientists operating safe laboratories are recognized for their work.

Biosafety and Occupational Medicine:

- Raise the stature of ESCHO in the CDC organization by staffing it with scientists with professional qualifications in research and/or laboratory safety as well as an understanding of requirements for compliance.
- Develop a division liaison program, where each division identifies individuals who can represent their needs to a centralized ESHCO committee.
- Expand the scope and capabilities of the Occupational Medicine Program to facilitate a more robust and active effort in monitoring employee health and in responding to laboratory incidents.

Progress Reporting and Laboratory Accreditation:

- CDC should track and report on its progress in establishing programmatic elements and processes recommended in this report in some formal way.
- CDC laboratories should go through an external review and accreditation process for all labs.

Regarding leadership, CDC believes that the laboratory is the “backbone” of public health. The agency identified funding to implement improvements in laboratory safety. A budget increase is requested to continue to improve safety and build capacity. Further, the new position of Associate Director for Laboratory Science and Safety (ADLSS) was established. This person will report directly to the CDC Director. Interviews of candidates are underway.

To address the recommendations pertaining to governance, CDC established a Laboratory Safety Review Board to conduct safety reviews of laboratory protocols for work in BSL-3 and BSL-4 laboratories. Oversight and support for this group will reside in the new Office of the ADLSS. Its goal will be to harmonize practices across the agency and will include representation from centers that have laboratory programs or have impact on laboratory programs.

The new Laboratory Safety Review Board is one way that CDC is addressing the recommendations regarding risk assessments. The board has convened and is reviewing laboratory procedures. The board has established set criteria so that each procedure meets certain requirements. The evaluation process showed that the laboratory staff had not been trained on how to perform risk assessments. A new Biological Risk Assessment Course was established to teach staff how to identify and mitigate risks in the laboratory. The feedback from the course was promising, and based on the evaluation of the first course, a new course was recently taught and data from that evaluation are being compiled. At the same time, a new policy is being developed to require the use of risk assessments for experimental work.

In the area of laboratory safety training, CDC is working to establish a standardized, competency-based, core safety training curriculum across the agency. Public health laboratory competencies were recently released and provide a framework for these efforts. Competencies have been identified and documented for standard, core laboratory safety training. A group created to address curriculum issues has evaluated 23 CDC safety training courses to map competencies and identify gaps. The group has developed a prioritized list of courses for a

standardized safety training curriculum based on needs and is developing learning objectives for priority courses. Additionally, the Laboratory Leadership Service (LLS), a new laboratory fellowship at CDC, has been established and will begin in July 2015. Plans are moving forward for development of a laboratory safety training curriculum.

In order to promote a culture of safety and incident reporting, CDC has implemented new and enhanced procedures for prompt reporting of laboratory incidents. The Laboratory Safety Helpdesk will allow for rapid reporting of incidents. Transparency and sharing lessons learned are important. Findings and recommendations related to CDC's laboratory-related incidents are shared on the internal and external CDC websites. CDC continues to engage with staff and with external partners. A new program known as "Laboratory Safety Champion" recognizes staff who promote laboratory safety and best practices. Staff are also recognized through a listserv to CDC's laboratory community.

The recommendation to raise the stature of ESCHO within CDC has led to consideration of permanent organizational changes after the ADLSS is named. In the meantime, new standard position descriptions have been created for occupational health scientists and quality scientists. Further, a representative from each of the laboratory centers has been named to a group that meets monthly to share concerns about laboratory safety and to discuss harmonizing safety practices across the agency.

CDC provides regular updates to its internal and external advisory groups and the public, remaining transparent regarding procedures. CDC is planning a pilot program for external accreditation. Five laboratories at CDC are participating in the program to attain external accreditation to International Organization for Standardization (ISO) standards. The process includes stakeholder engagement and is moving forward.

The next steps include continuing to address the ACD recommendations. The External Laboratory Safety Workgroup (ELSW) has been invited to a second site visit.

Discussion Points

Dr. Berns commented that he, Dr. Kanabrocki, and the rest of the ELSW has been gratified by CDC's response to the recommendations and by all of the progress that has occurred. He observed that CDC might experience more issues in this area than other agencies because CDC works with more of the really tough agents, frequently without initially knowing what they are working with. Secondly, work at CDC is done under great pressure to produce fast answers. In that situation, the temptation to engage in practices that are less than ideal can become overwhelming. He said he hoped that the agency was considering how to apply priorities so that the people doing the work understand that it is more important to do things right, even when they must be done expeditiously.

Dr. Goldman commented on the issue of custodianship and what happens to people's samples when they leave a facility. Sometimes reagents and other samples end up in boxes and no one knows what they are. She would appreciate hearing more about how to manage this challenge, as it would be helpful to other government agencies and institutions.

External Laboratory Safety Workgroup Update

Dr. Joseph Kanabrocki (External Laboratory Safety Workgroup Chair) explained that the charge to the ELSW was to evaluate safety programs in HHS laboratories, beginning with CDC. The group has since visited NIH and will visit FDA. The review of NIH included a review of the

implementation and execution of their biosafety and biosecurity protocols, and to propose suggestions for improvement.

ELSW includes biosafety professionals, physicians, microbiologists, investigators, and public health scientists. They have met via teleconference and in person at CDC and NIH. ELSW presented its observations regarding laboratory safety at CDC to the ACD in January 2015, and the ACD adopted the suggestions.

To begin the review at NIH, ELSW received a comprehensive set of documents, including safety protocols, governance structures, reporting structures, chains of command for reporting, performance evaluation, and other policies and mechanisms. ELSW made observations and suggestions in several areas. In other areas, the program is very strong and did not need further suggestions.

The NIH Intramural Division of Occupational Health and Safety (DOHS) Program is a model program for institutions supporting extramural NIH research as well as for other institutions and agencies. The program is well-established and steady, and this consistency contributes to its recognition as the sole source for safety guidance at the NIH. The commitment of NIH leadership toward laboratory safety is evident and is demonstrated at all levels examined by the ELSW. Safety awareness is viewed as an expectation, and this philosophy is exemplified via the involvement of senior NIH leadership in the safety infrastructure. Additionally, when financial resources are needed for unanticipated challenges in the realm of safety, the resources are identified and provided. An example of this approach is that the discovery of the smallpox vial led to the hiring of additional staff to exhaustively inventory every freezer, refrigerator, and cold room on the NIH campus during the biosafety stand-down.

Governance structures at NIH are supportive in maintaining a culture of shared responsibility and accountability across the Institutes. An electronic database system has been established and is a useful tool to communicate with regard to issues of research safety and compliance. The scope of protocols reviewed by the IBC includes recombinant microorganisms as well as work involving non-recombinant pathogenic microorganisms (Risk Group 2, 3 and 4); however, the IBC spends most of its time reviewing non-recombinant groups 3 and 4 pathogens, while the risk 2 group is delegated to the Institutional Biosafety Officer. The officer is very well-qualified, but the workload is large for one individual, so the ELSW suggested providing additional resources for this review.

IBC protocols are kept current by submission of amendments via an electronic protocol submission and approval system, but there is no expiration date or term limit on that protocol. Assigning an expiration date for each protocol not to exceed five years would promote safety. The ELSW suggested that scientists who serve on the IBC and other safety committees at NIH should be acknowledged for their service.

Risk assessment of research proposals are performed in a collaborative effort that involves the Principal Investigator, the IBC, the Biosafety Officer, and other DOHS staff. The responsibility is shared and not conducted only at the bench level or the program level. This approach is important. Because the IBC considers all rDNA protocols, but review of protocols involving non-recombinant RG 2 pathogens are delegated to the Biosafety Officer for review, it is not clear that the protocol-driven risk assessment process is a full risk assessment. The ELSW suggested that the IBC should be involved in the review of those projects at some level. The ELSW further suggested augmenting the risk assessment process to build in questions to continually ask Principal Investigators whether and how they have considered ways to approach

an experiment in ways that would further mitigate risks. ELSW also suggested that DOHS consider amending the risk assessment questions that are asked regarding Dual Use Research of Concern (DURC). The committee hoped that the potential impact of a release from containment would be considered.

DOHS is recognized across the NIH as the central authority in support and promotion of laboratory and research safety programs at the NIH. The division demonstrates an appropriate balance between regulatory compliance and facilitation of research activities. The office has strong leadership and staff are professional, competent, and dedicated. Under the DOHS, safety programs are consistent, respected and standardized across NIH. The workforce is stable, home grown, responsive, and supportive. Communications from the division are frequent and promote strong relationships. ELSW suggested that NIH consider developing a "Culture of Safety" survey tool similar to that developed by the CDC in an effort to accurately gauge areas for improvement in laboratory and research safety programs currently and over time.

Laboratory safety training is offered centrally through the DOHS via a variety of methods. All persons who work at or visit the NIH campus are trained. NIH Campus identification cards, and thus access to the NIH campus, are provided only upon completion of training. At the NIH, verification of competency for hands-on laboratory activities is currently limited to containment laboratories (BSL-3 and BSL-4). ELSW suggested expanding competency beyond those levels.

The NIH Intramural Occupational Medicine Program is a very strong, comprehensive occupational medicine program that serves as a model occupational health program for any biomedical research entity. Collaboration with other DOHS staff is clear.

Regarding systems and facilities, ELSW observed that the design of several of the BSL-2 laboratories were not optimal in providing separation of laboratory/research materials from desk and personal space assigned to investigators. The workgroup suggested considering that DOHS staff be involved in the design and remodeling of laboratories.

Regarding incident reporting, NIH staff conveys comfort in reporting of incidents with no fear of reprisals. This observation was consistently observed in interviews with staff at all levels of the NIH. An example of this comfort is the immediate reporting when the smallpox vial was discovered.

Staffing is a challenge for NIH, which employs a large number of contract employees. A robust on-boarding process includes training. Regarding internal communication mechanisms, laboratory managers may have experience in their own institute but may not have opportunities to meet with their counterparts at other institutes. There is an opportunity for a forum to share lessons learned and best practices.

The ELSW visit to the FDA in May 2015 will be followed by another visit to the CDC in the late summer or fall of 2015.

Discussion Points

Dr. Berns noted that the visit to NIH was interesting and rewarding. The set of observations and advice is upbeat, but the NIH is not perfect. Like any large research enterprise, NIH has made biosafety and biosecurity a priority for some time.

Dr. Greenberg asked whether the ELSW follow-up responsibilities will include evaluating how well CDC has addressed the recommendations that it made. A report from ELSW on this front to the ACD would be welcomed.

Dr. Kanabrocki replied that the group is interested in exploring CDC's response more deeply.

Dr. Berns said that NIH is acting on the suggestions and observations.

Dr. Kanabrocki added that ELSW has been impressed with the activities of the internal group at CDC. The ELSW focused on risk assessment and the role of the IBC, as well as training of bench staff. He advised that the protocol review activities of the internal committee be linked to the risk assessment and training activities of the IBC.

Dr. Frieden thanked Drs. Berns and Kanabrocki and the ELSW.

Motion

Dr. Richardson moved to approve the recommendations of the ELSW. Dr. Mullen seconded the motion. The motion passed unanimously with no abstentions.

Motion

Dr. Richardson moved to approve the minutes of the ELSW conference calls. Dr. Mullen seconded the motion. The motion passed unanimously with no abstentions.

Public Health – Health Care Collaboration Workgroup Update

Dr. Georges Benjamin (Public Health – Health Care Collaboration Workgroup co-chair) provided a recap of the Public Health – Health Care Collaboration (PHHCC) Workgroup recommendations that were approved by ACD.

The approved recommendations were:

- ❑ Support a more coordinated health system that links clinical care with public health.
- ❑ Fully leverage ACA requirements for non-profit hospitals and community health improvement.
- ❑ Promote a short set of performance measures to improve quality and delivery of preventive services across health systems.
- ❑ Develop guiding principles to support active engagement between public health and health systems.

The recommendations relate to bringing the public health and healthcare delivery communities closer in a variety of ways. The healthcare community includes providers, payers, and all those involved in the health enterprise in the US.

Mr. John Auerbach, Associate Director for Policy, CDC, addressed the ACD regarding progress on the recommendations.

The first area of progress is the development of a website for community health improvement (CHI). The purpose of the CHI Online Navigator is to provide hospitals and other community

stakeholders a "one-stop shop" for expert-vetted tools and resources. This effort is consistent with the PHHCC Workgroup's second recommendation. The website will be unveiled in the spring of 2015. It will include tools to help people involved in community health improvement and working with hospitals complying with the IRS provisions within the ACA. The website will make the case for collaborative approaches and offer a variety of resources, including case studies, tools to support success, a searchable database of interventions, and downloadable infographic fact sheets and slides. The developers of the website have worked with partners, hospitals, community groups, and public health groups to ensure that it reflects identified needs.

The second area of progress addresses the first and third recommendations. An unprecedented relationship has been developed with CMS, as CDC works closely with them to consider how to link public health, reimbursement and Medicare/Medicaid, particularly through the Innovation Center. CDC has also worked to establish relationships with the state Medicaid Directors individually in a manner similar to the agency's interactions with state public health commissioners. CDC has also engaged a variety of commercial payers and is working with self-insured employers.

These relationships are being developed to create greater capacity to promote prevention-oriented interventions for reimbursement. CDC CIOs have been asked to identify the evidence-based interventions that have been most effective in demonstrating positive health outcomes and/or cost savings. Eighteen interventions in the following six areas of health have been identified:

- ❑ Blood pressure control
- ❑ Tobacco use cessation
- ❑ Unintended pregnancy prevention
- ❑ Infection prevention
- ❑ Asthma control
- ❑ Diabetes prevention and control

The interventions are being presented to public and private insurers in order to promote their endorsement and inclusion of the interventions on their insurance service list. The relationships are progressing well. CDC health economists have met with actuaries in public and private insurance companies to understand the most compelling methodologies. CDC has convened a series of Think Tanks with insurers to test ideas, collect feedback, and promote the inclusion of prevention and public health approaches within healthcare.

There are several other areas of progress. The PHHCC Workgroup's input will be valuable in guiding ongoing implementation.

Discussion Points

Ms. Rosenbaum commented that the workgroup has been valuable at a time when CMS has been open to collaboration on issues of healthcare and public health. The IRS has jurisdiction over community benefit policy under the ACA and filed a report to the chair of the House Ways and Means Committee. In that report, the IRS doubles the estimate for community benefit spending. The official estimate is approximately $35 billion. By counting all hospital systems and not just single facilities, the estimate is over $62 billion. Currently, only approximately 5% of community benefit numbers are going toward community health improvement. The definition of "community health improvement" includes the cost of compliance issues on the part of hospitals, which includes costs of CHNAs. CDC has done yeoman's work in the past with the IRS. She hoped that with new data and with the help of the PHHCC Workgroup, the IRS can be

encouraged to ensure that community health improvement activities are really improving the health of the community.

Mr. Auerbach said that CDC takes seriously the importance of working with hospitals on their community benefits and honoring the requirements of the IRS provisions in the ACA.

Dr. Mullen commented that the work of the different ACD workgroups and subcommittees are aligning and converging in important ways, such as in health disparities and SDOH. The states engaging in SIM work may be able to work within their jurisdictions to define community benefits. Regarding the development of a concise set of quality measures, she noted that some process measures leading to outcomes are not reaching their targets. Million Hearts™, for example, could serve as a model for an approach that focuses not only on treating a disease, but also on reaching a goal so that as states adopt their quality measures, they are driving toward measurable efforts that result in impact.

Dr. Benjamin said that measuring success is a challenge. The Robert Wood Johnson (RWJ) Foundation is working on their concept of measuring what a "culture of health" means, and the Institute of Medicine (IOM) is soon to roll out a report on quality measures which they hope will be adopted as a way of standardizing quality measures across the country. HP 2020 also has measures. The challenges are how to coalesce around a means of measuring progress as a collective and how to make exact comparisons. Further, leveraging and coordinating funding across sectors to achieve goals in a holistic manner is important.

Mr. Auerbach agreed with the observations and noted that during the CMS conference he was attending, discussions were ongoing regarding appropriate quality measures. CDC is promoting a conceptual framework to ensure that the quality measures are not simply in terms of high quality of care provided in the traditional clinical setting; rather, the framework thinks of quality of care in three different categories: 1) In traditional clinical settings where quality measures should be prioritized and achieved, such as through the Winnable Battles and Million Hearts™; 2) Quality measures related to opportunities provided by moving away from fee-for-service toward value-based contracting, taking advantage of new flexibility to use evidence-based approaches that historically have not been paid for, such as using community health workers for delivery of some care; and 3) Community-wide evaluations that look at health indicators at a community level, as well as a set of evidence-based interventions that make a difference in improving health community-wide and globally. It will be a challenge to have appropriate quality measures for each of these categories as states and insurers think beyond traditional means of conceptualizing quality.

Dr. Benjamin noted that the CHI Navigator provides tools to help communities reach "the goal line." The tools include best practices, data, and suggested models for collaboration.

Dr. Bal noted that non-health dollars, such as transportation costs, are critical. This area is one in which CDC can provide assistance and information. The IRS has two categories: H1, community benefit; and H2, community-building. CDC "walks the walk" of community-building, and this work is not being done in 60% to 70% of hospitals.

Dr. Frieden added that CDC has been talking about the community benefit for years. It would be helpful to receive examples in which communities are actually benefiting.

Mr. Auerbach said that the CHI Navigator includes best practices and made those examples available.

Ms. Villar said that an ACD member will need to join the PHHCC Workgroup, as Dr. Benjamin was rotating off of the ACD.

Public Comment

Dr. Greenberg opened the floor for public comment in the room or on the telephone at 2:54 p.m. Hearing none, the agenda proceeded.

Closing Comments; Meeting Adjourned

Dr. Greenberg invited ACD members to share their final comments and ideas.

- Dr. Botchwey thanked ACD and CDC, noting that it had been an honor to serve on HDS and ACD. She looked forward to serving as she was called upon in the future.
- Dr. Mullen indicated her thanks and looked forward to being very involved on the ACD.
- Ms. Rosenbaum thanked CDC for a wonderful meeting, as always.
- Dr. Bal said that Dr. Frieden has done a tremendous job as CDC Director, particularly in the past year and enduring criticism for "doing a good job." His Winnable Battles mantra has been one of the most effective initiatives to come from CDC. He thanked Ms. Villar and Ms. Gayle Hickman.
- Dr. Fleming thanked Dr. Greenberg for his leadership of ACD and said that as the next ACD Chair he would be "stepping into big shoes." He thanked CDC and hoped that the personnel would have a moment to breathe.
- Dr. Goldman observed that the ACD is playing catchup as CDC is catching up, and she thanked the agency for a great meeting.
- Dr. Palacio thanked CDC and expressed that it had been a privilege and an honor to serve on the ACD.
- Dr. Benjamin thanked Dr. Frieden for his leadership. CDC continues to be a brand name and the agency that most people wish they could be affiliated with and well known by the public. He noted that on a recent trip to Cuba, he observed that CDC is a known brand there as well.
- Dr. Richardson expressed her thanks.
- Dr. Kanabrocki thanked Dr. Frieden for inviting him to join the ACD and thanked his ACD colleagues for the warm welcome. He said he expected to take more away from the experience than he would contribute, but is proud to be part of it.
- Dr. Berns congratulated Dr. Frieden on his responsiveness and agreed that it was an honor and pleasure to serve on the ACD.

Dr. Greenberg thanked Dr. Frieden and Ms. Villar for the privilege of serving on ACD. He added special thanks to Ms. Gayle Hickman, the steward of ACD. The ACD has "gotten its legs under it" in the past five years, having created a structure in which CDC brings high-priority issues and problems to the committee. Workgroups address these problems and report back to the ACD. CDC then follows up on the recommendations and the workgroups evaluate the progress. This level of engagement is impressive for an organization the size of CDC and represents great progress. He said he was happy to see CDC leadership at the table during the ACD meeting, and knowing that they are engaged in the process has galvanized the conversation.

Dr. Frieden thanked Dr. Greenberg for his leadership and chairmanship, which has improved CDC as an agency. He thanked the outgoing ACD members for their valuable input and guidance. He encouraged ACD members to share their ideas regarding issues that they would like to address at future ACD meetings.

With no further business posed or additional comments or questions raised, the meeting officially adjourned at 3:01 p.m.

Certification

I hereby certify that, to the best of my knowledge and ability, the foregoing minutes of the April 23, 2015, meeting of the Advisory Committee to the Director, CDC are accurate and complete.

_____ Date

_____
Alan Greenberg, MD, MPH
Chair, Advisory Committee to the Director, CDC

Attachment #1: Meeting Attendance

ACD Members Present:

Dileep G. Bal, MD, MS, MPH
District Health Officer
Hawaii State Health Department

Georges C. Benjamin, MD, FACP, FNAPA, FACEP (E), Hon FRSPH
Executive Director
American Public Health Association

Kenneth I. Berns, MD, PhD
Distinguished Professor Emeritus
Molecular Genetics and Microbiology
College of Medicine, University of Florida

Nisha D. Botchwey, PhD, MCRP, MPH
Associate Professor, School of City and Regional Planning
College of Architecture
Georgia Institute of Technology

Thomas A. Farley, MD, MPH
Chief Executive Officer
Public Good Projects

David W. Fleming, MD
Vice President, Public Health Impact
PATH

Lynn R. Goldman, MD, MS, MPH
Dean
Milken Institute School of Public Health
The George Washington University

Alan Greenberg, MD, MPH
Professor and Chair
Department of Epidemiology and Biostatistics
Milken Institute School of Public Health
The George Washington University
ACD Chair

Anthony B. Iton, MD, JD, MPH
Senior Vice President, Healthy Communities
The California Endowment

Joseph Kanabrocki, PhD, CBSP
Associate Vice President for Research Safety and Professor of Microbiology
The University of Chicago

Jewel M. Mullen, MD, MPH, MPA
Commissioner and State Health Officer
Connecticut Department of Public Health

Herminia Palacio, MD, MPH
Director
Human Capital and Leadership Teams
Robert Wood Johnson Foundation

Lynne D. Richardson, MD, FACEP
Professor and Vice Chair of Emergency Medicine
Professor of Health Evidence and Policy Population Health Science and Policy
Mount Sinai School of Medicine, Icahn School of Medicine at Mount Sinai

Sara Rosenbaum, JD
Harold and Jane Hirsh Professor
Milken Institute School of Public Health
The George Washington University
Department of Health Policy and Management

CDC Staff Present:

Kate Agin, MPA
Public Health Analyst
Office of the Director
Office for State, Tribal, Local, and Territorial Support

Ileana Arias, PhD
Principal Deputy Director

John M. Auerbach, MBA
Associate Director for Policy

Drue H. Barrett, PhD (CAPT, USPHS)
Lead, Public Health Ethics Unit
Office of Science Integrity
Office of the Associate Director for Science

Ursula E. Bauer, PhD, MPH
Director
National Center for Chronic Disease Prevention and Health Promotion

Beth P. Bell, MD, MPH
Director
National Center for Emerging and Zoonotic Infectious Diseases

Sherri A. Berger, MSPH
Chief Operating Officer

Brian Boyett, MS, BS
Public Health Analyst
Budget and Operations Management Activity
Office of the Chief of Staff

Patrick Breysse, PhD, CIH
Director
National Center for Environmental Health and Agency for Toxic Substances and Disease Registry

Leslie Dauphin, PhD
Interim Lead, Laboratory Safety
National Center for Zoonotic, Vector-Borne, and Enteric Diseases

John Decker, BPharm MS
Office of the Director
National Institute for Occupational Safety and Health

Jeff Efird, MPA
Deputy Director
Division of Viral Hepatitis
National Center for HIV/AIDS, Viral Hepatitis, STD, & TB Prevention

Thomas R. Frieden, MD, MPH
Director

Brian Graff, MPA
Senior Program Officer
Budget and Operations Management Activity
Office of the Chief of Staff, Office of the Director

Mary E. Hall, MPH
Associate Director for Science
Office of Minority Health and Health Equity
Alternate Designated Federal Officer, Health Disparities Subcommittee

Debra Houry, MD, MPH
Director
National Center for Injury Prevention and Control

Michael F. Iademarco, MD, MPH (CAPT, USPHS)
Director
Center for Surveillance, Epidemiology and Laboratory Services, OPHSS

Robin M. Ikeda, MD, MPH (RADM, USPHS)
CDC Deputy Director
Office of Non-communicable Diseases, Injury and Environmental Health
Director for Noncommunicable Diseases, Injury and Environmental Health

Harold W. Jaffe, MD, MA
Associate Director for Science
Office of the Director

Daniel B. Jernigan, MD, MPH
Ebola Response Incident Commander

Tom Kenyon, MD, MPH
Director
Center for Global Health

Rima Khabbaz, MD
CDC Deputy Director for Infectious Diseases
Director
Office of Infectious Diseases

John J. Kools, BS, MS
Office of the Director
Office of Public Health Preparedness and Response

Seth Kroop, MPH
Public Health Analyst
Office of Policy, Planning, and Evaluation
Office of Public Health Preparedness and Response

Judy Lipshutz, MPH
Public Health Analyst
Office of the Director
Office for State, Tribal, Local and Territorial Support

Katherine Lyon Daniel, PhD
Associate Director for Communication
Office of the Director

Eva Margolies, MPH
Associate Director for Planning and Policy
National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention

Jonathan (Jono) Mermin, MD, MPH (CAPT, USPHS)
Director
National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention

Judith (Judy) A. Monroe, MD, FAAFP
CDC Deputy Director, State, Tribal, Local and Territorial Support
Director
Office for State, Tribal, Local, and Territorial Support
Designated Federal Officer, STLT Subcommittee

Rebecca L. (Becky) Payne, MPH
Deputy Chief of Staff, Office of the Director
Office of the Chief of Staff

Ana Penman-Aguilar, PhD, MPH
Associate Director for Science
Minority Health and Health Equity Activity
Office of Minority Health and Health Equity

Stephen C. Redd, MD (RADM, USPHS)
Director
Office of Public Health Preparedness and Response

Chesley Richards, MD, MPH, FACP
CDC Deputy Director for Public Health Scientific Services
Director
Office of Public Health Scientific Services

Anne Schuchat, MD (RADM, USPHS)
Director
National Center for Immunization and Respiratory Diseases

Stuart Shapira, MD, PhD
Associate Director for Science
(representing Coleen A. Boyle, Director, National Center for Birth Defects and Developmental Disabilities)

Christa Singleton, MD, MPH
Office of the Director
Division of State and Local Readiness
Office of Public Health Preparedness and Response

Tom Skinner
Public Affairs Specialist
Division of Public Affairs
Office of Associate Director for Communication

Katrina Sloan, LCDR, USPHS
Division of Issues Management, Analysis and Coordination
Office of the Chief of Staff, Office of the Director

Phoebe Thorpe, MD, MPH
Office of the Associate Director for Science

Carmen Villar, MSW
Chief of Staff
Designated Federal Officer, Advisory Committee to the Director

Sarah Wiley, MPH
Senior Advisor, Office of Infectious Diseases
Interim Designated Federal Officer, Laboratory Safety Workgroup

Dianna Yassanye, BA, MS
Team Lead, Business Engagement
Office of the Chief of Staff, Office of the Director

CDC Foundation Participants:

Verla Neslund, JD
Vice President for Programs

Charlie Stokes
President and CEO

Chloe Knight Tonney
Senior Vice President for External Affairs

Betty Wolf
Vice President for Advancement

General Public:

Kendra Cox, MA
Writer/Editor
Cambridge Communication, Training, and Assessments

Attachment #2: Acronyms Used in this Document

Acronym	Expansion
AAP	American Academy of Pediatrics
ACA	(Patient Protection and) Affordable Care Act
ACD	Advisory Committee to the Director
ADLSS	Associate Director for Laboratory Science and Safety
AFM	Acute Flaccid Myelitis
AMD	Advanced Molecular Detection
AMR	Antimicrobial Resistance
APHA	American Public Health Association
APHL	Association of Public Health Laboratories
AR	Antibiotic Resistance
ART	Antiretroviral Therapy
ASTHO	Association of State and Territorial Health Officials
AU	African Union
AUR	Antimicrobial Use and Resistance
BSL	Biosafety Level
C. difficile	*Clostridium difficile*
CARB	Combating Antibiotic-Resistant Bacteria
CARE	Check and Report Ebola
CDC	Centers for Disease Control and Prevention
CERT	CDC Ebola Response Teams
CGH	Center for Global Health
CHI	Community Health Improvement
CHNA	Community Health Needs Assessment
CIOs	Centers, Institutes, and Offices
CMS	Centers for Medicare and Medicaid Services
CoV	Coronavirus
CRE	Carbapenem-resistant *Enterobacteriaceae*
CSF	Cerebrospinal Fluid
CSTE	Council of State and Territorial Epidemiologists
DGMQ	Division of Global Migration and Quarantine
DHS	(United States) Department of Homeland Security
DoD	(United States) Department of Defense
DOHS	Division of Occupational Health and Safety
DURC	Dual Use Research of Concern
EHR	Electronic Health Record
EIP	Emerging Infections Program
EIS	Epidemic Intelligence Service
ELSW	External Laboratory Safety Workgroup
EOC	Emergency Operations Center
EPA	(United States) Environmental Protection Agency
ESHCO	Environment, Safety, and Health Compliance Office
ETU	Ebola Treatment Unit
EU	European Union
EUA	End User Agreement
EVD68	Enterovirus D68
FDA	(United States) Food and Drug Administration

Acronym	Expansion
FETP	Field Epidemiology Training Program
FY	Fiscal Year
GHS	Global Health Security
GHSA	Global Health Security Agenda
GWG	Global Work Group
HAI	Healthcare-Associated Infection
HDS	Health Disparities Subcommittee
HHS	(United States Department of) Health and Human Services
HIV/AIDS	Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome
HP	Healthy People
IBC	Institutional Biosafety Committee
ICAR	Infection Control Assessment Response
ICU	Intensive Care Unit
IHR	International Health Regulations
IOM	Institute of Medicine
IRS	Internal Revenue Service
ISO	International Organization for Standardization
IT	Information Technology
IV	Intravenous
JPHMP	Journal of Public Health Management and Practice
LLS	Laboratory Leadership Service
LRN	Laboratory Response Network
MDR	Multidrug Resistant
MERS	Middle East Respiratory Syndrome
MMR	Measles, Mumps, and Rubella vaccine
MMWR	*Morbidity and Mortality Weekly Report*
MOH	Ministry of Health
MSF	Médecins Sans Frontières/Doctors Without Borders
NARMS	National Antibiotic Resistance Monitoring System
NCD	Noncommunicable Disease
NCEZID	National Center for Emerging and Zoonotic Infectious Diseases
NCIRD	National Center for Immunization and Respiratory Diseases
NCSL	National Conference of State Legislatures
NGA	National Governors Association
NHSN	National Healthcare Safety Network
NIH	National Institutes of Health
NIOSH	National Institute for Occupational Safety and Health
PCR	Polymerase Chain Reaction
PDO	Prescription Drug Overdose
PEPFAR	President's Emergency Plan for AIDS Relief
PHAB	Public Health Accreditation Board
PHAP	Public Health Associate Program
PHEC	Public Health Ethics Committee
PHHCC	Public Health – Health Care Collaboration (Workgroup)
PICH	Partnerships to Improve Community Health
PPE	Personal Protective Equipment
PPHF	Prevention and Public Health Fund
REP	Rapid Ebola Preparedness

Acronym	Expansion
RITE	Rapid Isolation and Treatment of Ebola
SARS	Severe Acute Respiratory Syndrome
SDOH	Social Determinants of Health
SIM	State Innovation Models
SME	Subject Matter Expert
SNS	Strategic National Stockpile
STLT	State, Local, Tribal, and Territorial (Subcommittee)
STRIVE	Sierra Leone Trial to Introduce a Vaccine Against Ebola
TB	Tuberculosis
UK	United Kingdom
USAID	United States Agency for International Development
USDA	United States Department of Agriculture
WHO	World Health Organization